Public Health England

Protecting and improving the nation's health

Newborn Pulse Oximetry Screening Pilot

End Project Report

Version 1.0, May 2016

Public Health England leads the NHS Screening Programmes

About Public Health England Screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the 4 UK countries. The Screening Quality Assurance Service (SQAS) ensures programmes are safe and effective by checking that national standards are met.

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Abbreviations

ANNP	Advanced Neonatal Nurse Practitioner
BiPAP	Bilevel positive airway pressure
CHD	Congenital Heart Defect
CCHD	Critical Congenital Heart Defect
CI	Confidence intervals
CPAP	Continuous positive airways pressure
CRP	C reactive protein
CVS	Cardiovascular system
CXR	Chest x-ray
ECE	Expedited clinical examination
FBC	Full blood count
FP	False positive
FN	False negative
HTA	Health Technology Asessment
MLU	Midwifery Led Unit
NICE	National Institute for Health and Clinical Excellence
NICU	Neonatal Intensive Care Unit
NIPE	Newborn and Infant Physical Examination
NNU	Neonatal unit
NPS	Northgate Public Services (UK)
PEC	Paediatrician with expertise in cardiology
PO	Pulse oximetry
PPHN	Persistent pulmonary hypertension of the newborn
TN	True negative
TP	True positive
TTN	Transitient tachypnoea of the newborn
T21	Trisomy 21
UAT	User Acceptance Testing
U&E	Urea and electrolytes
US	Ultrasound

Abbreviations of cardiac conditions

AS Aortic stenosis
ASD Atrial septal defect
CHD Congenital heart defect
CoA Coarctation of the aorta
DORV Double outlet right ventricle
HLH Hypoplastic left heart
IAA Interrupted aortic arch
PA Pulmonary atresia
PDA Patent ductus arteriosus
PS Pulmonary stenosis
TA Tricuspid atresia
TAPVD Total anomalous pulmonary venous drainage
TGA Transposition of the great arteries
TOF Tetralogy of Fallot
VSD Ventricular septal defect

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Glossary

The glossary defines terms that are consistent across NHS screening programmes. The scope of each defined term as it applies to a particular screening programme is detailed separately for each screening programme.

A broken underline indicates that a term is used according to its definition in this glossary. Where terms from the glossary are used without a broken underline, their common English meaning can be assumed; except where context determines otherwise. Definitions include all forms of the defined term; so 'tested' and 'testing' refer to the definition of 'test'.

Term	Definition
accept	A response to an offer which indicates that a screening subject is willing to proceed with a screening encounter/event. Acceptance may be inferred from conduct provided that an offer has been made. In the case of newborn screening programmes, a responsible parent/guardian can accept screening on behalf of the subject baby.
acceptance of offer	The proportion of those offered screening who accept the offer. Low acceptance of offer might indicate that: i) the offer is not being communicated or delivered effectively (no response); and/or ii) screening is not deemed necessary or desirable by an entitled population (declined)
communication	An interchange that the subject is capable of understanding and acting upon. This may be in a variety of formats including verbal and/or written.

Term	Definition
coverage	The proportion of those eligible for screening who are tested and receive a result. Coverage is a measure of timely screening to an eligible population. Low coverage might indicate that: i) not all eligible people have been offered screening ii) those offered screening are not accepting the test iii) those accepting the test are not being tested
effective timeframe	The period of time within which a screening test can be delivered such that a result is most likely to be obtained. The effective timeframe for a test is usually specified by the relevant screening programme.
eligible	The population that is entitled to an offer of screening. The criteria for eligibility may be administrative, demographic, clinical, or any combination of these, and may take into account individual circumstances such as time of presentation to the screening service.
population	The overall population for which a screening service is responsible.
maternity service	A co-ordinated network of healthcare professionals contracted to or working under the policies and procedures agreed with a single acute Trust, with collective responsibility for the provision of antenatal, intrapartum and postpartum care. A single maternity service may include: obstetric-led maternity units

Term	Definition
	midwifery-led maternity units units responsible for the management of homebirths newborn intensive care units (NICU) special care baby units (SCBU) paediatric intensive care units (PICU)
refer	The process of securing further diagnosis/specialist assessment following a screen positive test. The date of referral is when the request for further assessment is made to the appropriate specialist.
result	A formal and completed assessment of the risk of a condition being screened for in a subject. A result will be screen positive or screen negative. Inadequate or inconclusive tests indicate a failure to obtain a result, and are ***not counted*** within coverage. In these cases the subject may be offered a repeat screening test.
screen positive	An indication following a test that the condition being screened is high-risk/suspected in a subject.
screening	Testing people who do not have or have not recognised the signs or symptoms of the condition being tested for, either with the aim of reducing risk of an adverse outcome, or with the aim of giving information about risk.
test	A screening encounter/event leading to the determination of an outcome. Test outcomes can be screen positive, screen negative, insufficient or inconclusive.

Term	Definition
uptake	The proportion of those offered screening who are tested and receive a result. Uptake is a measure of the delivery of screening in the population to which it is offered. Low uptake might indicate that: i) those offered screening are not accepting the test ii) those accepting the test are not being tested

Pulse oximetry Non-invasive technique to measure the amount of oxygen-saturated haemoglobin (oxygen saturations – SpO_2) usually in the capillaries of an extremity i.e. hand or foot in the newborn.

Pre-ductal A site normally receiving its blood supply proximal to where the ductus arteriosus enters the aorta. Measurement of pre-ductal oxygen saturations (SpO_2) is obtained from the right hand.

Post-ductal A site normally receiving its blood supply distal to where the ductus arteriosus enters the aorta. Measurement of post-ductal SpO_2 is obtained from the foot.

Differential The percentage difference between the pre-ductal and post-ductal PO measurement

CEX system Clinical evaluation exercise

Executive summary

Background

Congenital heart defects (CHD) are the most common group of congenital malformations and one of the leading causes of infant death in the developed world. Early detection of critical CHD (CCHD) – that which causes death or requires invasive intervention before 28 days of age - may improve outcome. Current routine screening for CHD relies on a mid-trimester fetal anomaly ultrasound scan, involving imaging of the heart chambers, and a postnatal clinical examination involving assessment of the cardiovascular system. Both of these have a relatively low detection rate and a significant number of babies are discharged from hospital before CCHD is diagnosed. A proportion of these may die or present in such a poor clinical condition that the outcome, despite treatment, is compromised.

Pulse oximetry (PO), as an additional screening test to identify babies with CCHD prior to acute clinical deterioration has been widely reported and routine screening is being taken up or considered by many countries. In 2013, approximately 20% of maternity units in the UK were using some form of PO screening for CCHD; however the screening pathways varied significantly and little outcome data were available. Of the remaining units who were not screening at the time, approximately 70% expressed an interest in screening but either reported potential barriers to implementation or preferred to wait for national guidance. Following the public consultation in 2013 and the publication of further UK evidence, the UK NSC proposed that the feasibility and impact of PO screening (in a wider clinical context) be examined in a pilot study involving maternity units across England. This report describes the results of the six month pilot.

Aims and objectives of the pilot study

Aims:

to evaluate the feasibility of implementing newborn PO screening on NHS services
to establish the effect on clinical services when PO screening is undertaken as part of the newborn and infant physical examination NIPE Programme.

Objectives:

To:

- identify existing PO screening pathways already in use within the defined participating Trusts
- describe the variation between the maternity services within a defined number of Trusts in respect to clinical workload, protocols and resources associated with existing routine PO screening carried out on newborns.

- describe the variation between those Trusts in respect to clinical workload, and resources associated with implementing routine PO screening as a new screening test carried out on newborns
- audit screening outcomes in all eligible babies: all cardiac diagnoses, non-cardiac diagnoses in screen positive babies, referrals after a positive cardiovascular screen following NIPE or PO, deaths within 1 month of birth, through the collection of data and analysis
- develop information for parents and resource media for health professionals to be used in the pilot
- support delivery of training for health care professionals involved in newborn screening using PO in the pilot.

Participating Trusts

Fifteen Trusts were selected for the pilot - seven were already offering PO screening for newborn babies and eight had not previously introduced screening. The Trusts were chosen based partly on their willingness to participate, but mainly on the range of size of Trusts (number of deliveries per annum), the level of access to neonatal intensive care and paediatric cardiology and the geographical location. The 15 participating Trusts ranged from high-volume, urban tertiary units to low-volume rural midwifery led units and were divided into two groups. Group A – seven Trusts who were already performing PO screening, but agreed to look to change where possible the existing newborn PO screening pathway (see Figure PO 1) for the duration of the pilot. Group B – eight Trusts who had not previously performed PO screening.

Newborn pulse oximetry screening pilot methodology

The pilot was conducted over two phases:

Phase one

Completion of baseline assessment questionnaire and retrospective data collection from a predefined dataset - commenced on 27th February 2015

Phase two

Pre phase 2 all pilot Trusts undertook a short ‘baseline’ prospective data collection phase prior to change or implementation of the pilot screening pathway. This was based on existing screening provision commenced June 2015 for one month:

Pilot PO screening undertaken 1st July – 31st December 2015:

- alignment to the pilot screening pathway in those Trusts already undertaking newborn PO and collect data to record impact of any change (Group A)
- the introduction of PO screening as a new element of the NIPE programme in selected pilot Trusts and collection of data to record impact of any change (Group B)

Retrospective and prospective data collection

All the participating pilot Trusts attempted to collect six months of retrospective data as per pilot dataset and one month of prospective data relating to number of deliveries, number of neonatal unit admissions and the number of cardiac, respiratory and infective conditions that were diagnosed (in addition to other data). Prospective data were collected on the NIPE SMART IT system (in a small number of Trusts the IT system was introduced just prior to the implementation of PO screening). One Trust did not use NIPE SMART but did collect data on their local EPIC IT system (HIS). Prospective data collected in Phase two provided some limited information on the impact of change in introducing PO as a new screening test and on those Trusts who aligned to the pilot screening pathway. Despite great efforts by the pilot Clinical Leads in the participating Trusts and the NPOSP Project Team, the data provided by the Trusts were incomplete and could not be usefully analysed. A direct comparison of clinical workload including number of admissions to the NNU and investigations undertaken was not possible. However, the prospective data did inform the coverage rate and the referral pathway for screen positive cases.

Agreed newborn pulse oximetry pilot screening pathway

The pilot Project Board for NPOSP agreed a pilot screening pathway which was disseminated to all participating pilot Trusts. The pathway was based on the West Midlands Pulse Ox Study pathway with minor modifications. All pilot trusts agreed to attempt to adhere to the pilot screening pathway as much as possible but some were mindful of the potential impact on the local clinical service and existing service models.

Summary of Key Points

- 15 Trusts from all over England were recruited to participate (see Appendix 3)
- phase 1 of the pilot commenced 27th February 2015
- phase 2 active screening phase ran from 1st July to 31st December 2015
- 157 pulse oximeters were provided to Trusts for use in the pilot.
- funding for data clerk function was provided to support data collection and submission
- no additional staff were employed by the pilot Trusts to undertake PO screening
- almost 33,000 babies underwent newborn PO screening as part of the pilot.

Summary of Key Data Findings

The following tables provide the key data findings from the pilot:

Table 1: PO screens performed as part of the pilot

Total number of PO screens performed	32,836 (complete screens)
Total number screen negative cases	**32,597**
Total number screen positive cases	**239**
Overall screen positive rate (SPR)	**0.73%**
Number of Critical Congenital Heart Disease (CCHD) cases identified	**8**
Total number of known false screen negative cases	**2**

Table 2: Critical congenital heart disease diagnoses identified by PO screening

CCHDs
Coarctation of the Aorta (CoA)
Critical pulmonary stenosis (PS), ventricular septal defect (VSD) and patent ductus arteriosus (PDA)
Critical PS x 2
Transposition of the great arteries (TGA) with VSD
TGA
Supracardiac total anomalous pulmonary venous drainage (TAPVD)
Hypoplastic aorta/CoA (hypoplastic left heart syndrome) and mixed TAPVD

Table 3: False screen negative diagnoses missed by PO screening

False screen negative cases
CoA
Hypoplastic left heart syndrome

Clinical support and equipment

All the participating pilot Trusts were visited by the pilot Project Team to meet with local clinical PO pilot lead and to facilitate a local stakeholder meeting. Trusts then received the pilot screening pathway and the pilot educational information resources to support delivery of in - house training and provide parents with information regarding the pilot. Pulse oximeters were provided to all the participating pilot Trusts on a pro-rata basis depending on the number of anticipated deliveries. Pulse oximeter training was provided by the manufacturer's training team as part of their contractual obligations.

Target outcomes of newborn PO screening pilot

In order to fully evaluate the performance of the PO screening programme in detecting all structural CHD, the outcomes to be monitored prospectively before and after the introduction of PO in pilot sites included:

Cardiac diagnoses (all structural cardiac diagnoses)
Non-cardiac diagnoses – all diagnoses with hypoxaemia noted before discharge (including at screen) or on readmission (if within 24 hours after birth)
Deaths within 30 days of birth.

Primary targets of screening

The primary outcome for an evaluation of the test accuracy of PO screening is timely diagnosis, defined earlier as diagnosis of a life-threatening CCHD before collapse or death occurs. Babies with non-critical CHDs that do not necessarily lead to preoperative clinical deterioration may also benefit from earlier detection as this allows parents and clinicians to fully discuss and prepare a management plan.

The following CHDs are key targets of screening:

HLH/single ventricle
PA (with IVS)
TGA
IAA

The following defects also have the potential to lead to collapse and are targets of screening:

TAPVC
COA
AS
TOF

As one of the aims of the pilot was to determine the workload associated with positive screen results using PO, it was appropriate to record the detection of all CHDs. The proposed target lesions for screening (HLH, PA, TGA, IAA, TAPVC, COA, AS and TOF) are those which have the potential to collapse, and data on the timing of surgery were collated so that the outcomes of the pilot could be appraised in terms of 'critical' CHD.

Progress of the pilot study

After considerable preparation work from September 2014 PO screening started in all pilot Trusts and was completed to time and target (1st July 2015 – 31st December 2015).

Newborn PO screening pilot data findings and related workforce issues

Over the six month pilot period 38,828 babies were born in the participating pilot Trusts. Of these, 2,513 (6.2%) were ineligible for screening. A total of 32,836 babies (90.4%) who were eligible underwent PO screening as recorded on the NIPE SMART IT system (in 14 Trusts) or the EPIC HIS (in one Trust).

Of the 3,479 eligible babies who were not screened, 996 (2.6%) were recorded as being missed and in 47 (0.12%) cases parents declined screening. The remaining 2,436 (70% of unscreened eligible babies) had inadequate data recorded to assess the result of screening – in the majority of these (91%), no data was recorded on the NIPE SMART IT system. Discussion with the pilot Trusts indicated that a large number of these babies had been screened but the result not entered onto the system. However the precise numbers where this was the case is not available.

Only 52% of all babies received PO screening within the suggested target time of 4-8 hours, but 78% were screened within 12 hours and only 8.5% were screened after 24 hours. Reasons for these deviations from the agreed pathway were mainly relating to existing service model, time pressures and staffing issues.

Three trusts in Group A did not change from their established local pathway to the agreed pilot screening pathway. This resulted in very early screening (under 4 hours) for one Trust or late screening for two Trusts. PO screening in one Group B Trust was undertaken by the hearing screeners. It was not possible to determine the exact timing of lateness of the screening results.

Of the 32,836 babies who underwent PO screening 96.6% passed (in line with the PO pilot pathway) on the first screen, 3.1% had a result requiring a repeat screen. Of these 87% passed the repeat screen. Overall 239 babies (0.73%) had a screen positive result.

Of the 239 screen positive babies, 115 (48%) were admitted to the NNU for further assessment. Of the screen positive babies who were not admitted to NNU, 97% had transitional circulation, 2 babies had culture negative sepsis and in 2 babies the final diagnosis was not recorded.

The pilot screening pathway recommended that all screen positive cases were seen by a senior clinician. This occurred in 80% of cases. The number of screen positive cases within Trusts ranged from 0 to 52 (mean 16) which equates to an average of approximately one screen positive case every 11 days. (range 0-2 per week). Why the remaining 20% were not reported to have been seen by a senior clinician in line with the screening pathway is not clear, and is likely to be related to lack of availability or competing clinical demands.

Of the 114 babies admitted to NNU, eight babies (7%) had a CCHD and 86 (75%) had a significant illness which required medical intervention (43 cases of culture negative sepsis, 30 respiratory disorders, 6 PPHN, 3 culture positive sepsis and 5 non-critical CHDs). Only 22 babies (9% of all screen positives; 0.07% of all screened babies) were healthy babies who were admitted to NNU.

Most babies admitted to NNU (106; 93%) underwent investigations; the majority were blood tests and chest x-rays. Only 32 babies (28% of those admitted, 10% of all screen positives) underwent echocardiography.

Sixty-six percent of screen positive babies admitted to NNU stayed for longer than 24 hours and 47% required intensive or high dependency care. Fifty-eight babies required supplementary oxygen and eighteen required some form of positive pressure ventilatory support (six were ventilated and ten received CPAP/BiPAP)

Two babies with critical CHD and one baby with a serious CHD who were screen negative – i.e. passed PO screening and were false negatives (- they also passed antenatal fetal anomaly ultrasound screening and NIPE screening examination o). One of the CCHD babies died and the other presented in a collapsed state.

The screen positive rate was consistent with previous early PO screening studies as was the range and proportion of cardiac and non-cardiac diagnoses in screen positive cases.

Delayed Discharge

A total of 7 Trusts reported a delay in discharge due to repeat screen procedure. Out of a total of 897 repeat screens performed 12 (1.3%) resulted in a delay in discharge for screen positive babies. Of the 239 screen positive babies discharged was not delayed in 115 (48%).

Discharge was reported as delayed in 68 (28%) but of these, over half (53%) had a significant clinical diagnosis which is highly likely to have delayed discharge anyway. Overall, discharge was reported as inappropriately delayed in 32 babies (13% of all screen positives). These babies all had transitional circulation.

Post-pilot questionnaire

A post-pilot questionnaire was completed by all the pilot Trusts following a face-to-face meeting and semi-structured interview with a member of the pilot Project Team.

The main findings were as follows:

- No Trust described that organisational changes were necessary for the successful implementation of the pilot.

- Some Trusts modified the agreed pilot screening pathway. Five Group A and one Group B Trust failed to adhere precisely to the pilot screening pathway; specifically they did not perform PO screening at 4-8 hours after birth but varied the timing to suit staff availability, timing of discharge and integration with existing NIPE screening model. Two Group A Trusts who already had a PO screening test as part of the NIPE exam continued with this model and did not adopt the pilot screening pathway which required the PO screen to be undertaken at 4-8 hours after birth.

- Ninety-four percent of Trusts stated that they did not identify an increase in the number of admissions to NNU following the introduction of PO screening. One Trust described an increase in admissions with one Consultant considering halting PO screening due to an over capacity of cots at that particular time. However the rest of the Consultant group decided that the benefits of PO screening outweighed the risks and continued with the pilot.

- Trust staff were not aware of any increase in the number of echocardiograms or cardiology consultations requested during the pilot.

- Some Trusts did experience staffing and time constraints in order to adhere to the pilot screening pathway:

- All Group B Trusts undertook an extensive local training programme

- Some Trusts experienced issues with the understanding and use of the NIPE SMART system

- One Trust did not consider the extra workload involved in offering PO screening was justified by the number of cardiac cases identified

- No trusts employed additional staff to implement PO screening, however, one Group B Trust would consider employing additional nursery nurses.

- No significant concerns were identified to suggest that PO screening would be unacceptable to parents. Three Group A Trusts did not alter the established local pathway for the pilot and was only willing to do so if a new pathway was based on a national recommendation to implement a standardised screening pathway

Newborn pulse oximetry screening pilot conclusions

The following form the conclusions made from the data presented from this newborn pulse oximetry screening pilot End Project Report.

During the pilot almost 33,000 babies (including homebirths) were screened in 15 Trusts following the introduction of PO screening or re-alignment of an existing screening programme to the PHE PO screening pathway.

Just over 90% of all eligible babies had pulse oximetry screening and a result entered onto the NIPE SMART IT system or local hospital information system. In babies where data was not entered a number of issues were identified relating particularly to the use of the NIPE SMART system. It is likely that more babies were screened but the result was not entered into this system.

The timing of first screening followed the agreed screening pathway in the majority of cases; however there were important exceptions to this which were mainly due to some Group A Trusts continuing with their existing service model (non-alignment with the agreed pathway). Although the vast majority of screens outside the suggested timings were within clinically acceptable limits, staff responses suggested that in the cases where screening was outside the agreed timings staff availability and timing constraints contributed to the majority of these deviations. Timing of the second screen was often outside the agreed pathway due similar constraints but this does not appear to have had clinical consequences or increased a delay in discharge.

The PO screen positive rate was 0.73% which is consistent with previously published UK studies employing early screening (within 24 hours).

In keeping with previous studies, a significant proportion of PO screen positive babies had an important clinical condition but only a minority had the target condition of CCHD. Earlier screening (within 24 hours) results in a higher proportion of babies detected with a clinical condition but at the expense of a slightly higher screen positive rate. Forty-eight percent of screen positive babies were admitted to the NNU and eight babies with the target condition of CCHD were identified by screening. A further 86 babies with significant non-cardiac conditions were also identified. The rate of true false positives i.e. babies who were completely healthy and were admitted to NNU was very low but two babies with target conditions were missed. It is clear that PO screening identifies many more babies with a non cardiac condition than those with the target condition of CCHD. The test accuracy of PO screening for these conditions is unknown and there is a possibility that some of the babies are ‘labelled’ with an

incorrect medical diagnosis thus creating the potential for over diagnosis. An attempt was made as part of the pilot to reduce this possibility but it cannot be completely excluded

There was little evidence of additional significant harm to the majority of babies who had a screen positive outcome. It is possible however, that as above some babies underwent unnecessary admission and investigation as a result of testing screen positive, particularly some of those with culture-negative sepsis, these are likely to be in a minority. There was little evidence of clinical services, including midwifery, neonatal and paediatric cardiology being overwhelmed by the consequences of PO screening. The number of screen positive cases within Trusts ranged from 0 to 52 (mean 16) which equates to an average of approximately one screen positive case every 11 days. (range 0-2 per week). Although additional work for staff and occasional pressures on admissions was described by the pilot Trusts, all were able to undertake PO screening and successfully manage the screen positive babies.

Although the majority of screen positive babies were seen by a senior clinician as recommended in the pilot screening pathway, this did not happen in every case. There were no recorded clinical consequences of this omission. A minority of screen positive babies underwent echocardiography and the additional impact on cardiological services appears to have been minimal.

No major problems with equipment were highlighted and the pulse oximeter monitors used appeared to have been fit for purpose overall. All participating Trusts have continued routine PO screening following completion of the pilot without further additional funding.

Overall the PO screening pilot appears to have achieved the main aims of demonstrating feasibility of screening without causing a significant overload to clinical services.

Learning points

The pilot generated a number of important learning points:

- The collection of routine retrospective data regarding the number of admissions to neonatal units with specific conditions and the outcome of those conditions is a challenge. As a result, the comparator data preceding the commencement of the pilot was inadequate. A better comparator which would enable a direct comparison of the effect of PO screening on admissions and work load is required.

- Although pilot Trusts who had not engaged in PO screening previously were largely able to follow the agreed screening pathway, Trusts who had an established screening model found it more difficult to adapt to the agreed pathway.

- Screening within a tight timeframe was a challenge for most of the pilot Trusts but a clinically acceptable screening timeframe is largely achievable.

- The coordination of performing PO screening and recording the result on the NIPE SMART system was challenging for some of the participating Trusts. There appeared to have been a ‘learning curve’ and performance was better at the end than at the beginning, however, further consideration in this area is required.

- The majority of babies who screened positive were healthy and did not require admission to the neonatal unit. Further modification of the screening pathway may allow a reduction in the proportion of screen positives.

- Although PO screening identifies most babies with the target condition it still misses some babies and it is important that both clinical staff and parents are aware of the limitations of the test.

- Most screen positive babies who are admitted to NNU have a non-cardiac condition. (i.e. not the target condition) In the majority, the early identification of these conditions is of clinical benefit and a potentially important additional benefit of screening. However, the balance of risk to benefit for these babies and the potential cost implications needs to be carefully considered.

- Echocardiography does not appear to be necessary for all screen positive cases with use of clinical judgement resulting in a minority requiring this test.

- The true cost and cost effectiveness of PO screening was not defined within the pilot study and further health economic analysis is required to precisely define this.

Newborn pulse oximetry screening pilot recommendations

Following on from the data analysis of the pilot and the feedback received from the pilot Trusts relating to the agreed pilot screening pathway, the pathway could be modified in the following ways:

- timing of screening should continue to aim for first screen within 4-8 hours but a degree of flexibility earlier or later (up to 18-24 hours) is acceptable and could be considered .This may have the effect of the screening test being more easily embedded within routine clinical practice

- a second retest (third screen) could be considered in babies who are screen positive but have a normal clinical assessment and no additional risk factors. This would potentially have the effect of reducing the number of screen positive cases

Additional recommendations from the pilot:

- health economic analysis is necessary to define further the true cost of introducing PO screening

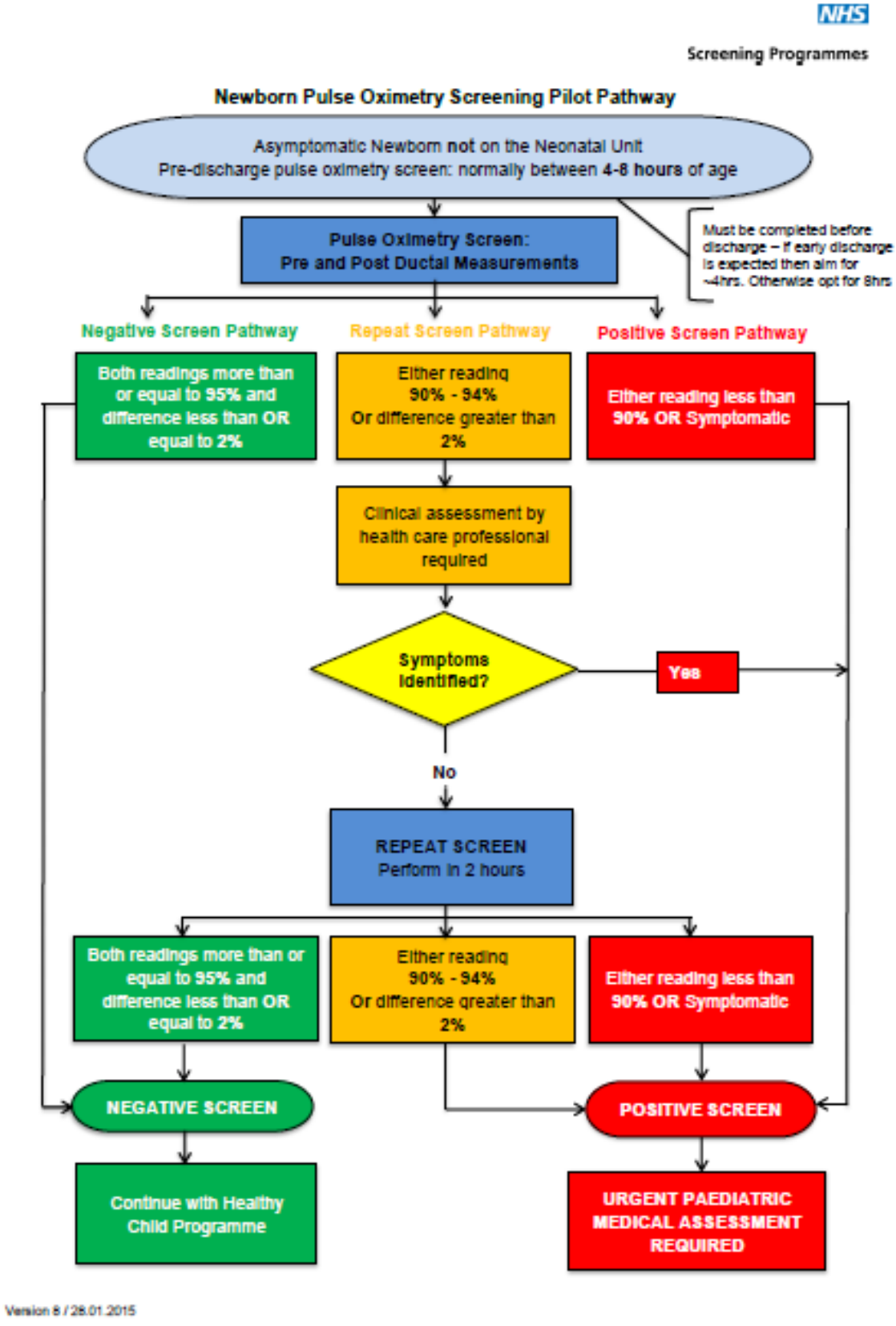
- further analysis of the effect of PO screening on admissions to NNU (particularly the non-cardiac conditions) would be beneficial including using possible use of data generated by the UK Neonatal Data Analysis Unit (NDAU)

- the risks and benefits of linking PO screening to the NIPE examination could be explored further and recommendations made

- the entry of PO screening results and relevant risk factors to one IT system (or use of interoperability messaging technology) would be beneficial to increase the recording of screening results. Additional training and support following the introduction of the NIPE SMART for the entry of the PO screen results would be advantageous

The pilot has demonstrated that in general, it is feasible to introduce PO screening in an NHS environment, however there are important clinical considerations as highlighted above. The routine introduction of PO screening could be considered once these issues have been satisfactorily resolved.

Figure PO 1: Newborn PO Screening Pathway



Section One

Newborn Pulse Oximetry Screening Pilot Background

This report outlines the process undertaken to deliver the Public Health England (PHE) newborn pulse oximetry screening pilot (NPOSP) between February and December 2015. It also includes the data findings, lessons learned and recommendations for future consideration in relation to the potential delivery of a newborn PO screening programme in England.

Background and Literature Review

Congenital heart defects (CHDs) are the most common congenital abnormality and a leading cause of infant death in high-income countries - accounting for up to 40% of deaths from congenital abnormalities (more than any other type of malformation) and 3-7.5% of all infant deaths.[1]

The reported incidence of CHD is between 4-10/1000 livebirths. The estimated incidence of ductal-dependent critical congenital heart defects (CCHDs) – defects leading to death or requiring invasive intervention within 28 days of life - is between 2-3 per 1000 livebirths.[1, 2]

Early detection of CCHDs reduces the risk of acute cardiovascular collapse, acidosis and death and improves outcome following surgical intervention.[2, 3, 4]

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[1] Ewer AK, Furmston AT, Middleton LJ, et al. Pulse oximetry as a screening test for congenital heart defects in newborn infants: a test accuracy study with evaluation of acceptability and cost-effectiveness. Health Technol Assess 2012; 16:1–184.

[2] Mahle WT, Newburger JW, Matherne GP, et al. Role of pulse oximetry in examining newborns for congenital heart disease: a scientific statement from the AHA and AAP. Pediatrics 2009; 124:823–836.

[3] Hoffman JIE, Kaplan S. The incidence of congenital heart disease. J Am Coll Cardiol 2002; 39:1890–1900.

[4] Hoffman JIE. It is time for routine neonatal screening by pulse oximetry. Neonatology 2011; 99:1–9.

Screening for CCHD

Current routine screening methods for identifying babies with CHD include the newborn physical examination (NIPE) and antenatal anomaly ultrasound scanning, however both methods have relatively low detection rates. In one UK study, 15% of infants with CHDs who died before 12 months of age had a CHD that was undiagnosed prior to death.[5] Failure to diagnose a critical CHD prior to discharge from hospital occurred in up to 26% of infants in Swedish over an 8-year period, with an increase in infants discharged without diagnosis over the study period.[6] In UK studies, 25–30% of infants with potentially life-threatening conditions[7] and almost 80% of infants with obstructive left heart defects (the main causes of death from an undiagnosed CHD after discharge and before diagnosis) left hospital undiagnosed.[8] Similar data have been reported in the USA; 1 in 10 infants with a CHD dying in the first year of life did not have the malformation diagnosed before death and, of the infants who died in the first week of life, one-quarter did not have a diagnosis before death.[9] Death at home or in hospital emergency rooms occurred in 50% of infants with undetected critical CHDs.[10]

Although antenatal ultrasound detection offers the opportunity to identify CCHD before birth – and thus plan delivery and immediate intervention – the overall performance of this screening test is still very low. Recent data from the UK indicates that although detection rates are improving, in 2013 only 46% of all cardiac defects receiving surgical or catheter intervention in the first year of life were diagnosed antenatally and although precise data are not available it is likely that this would include a significant proportion of large septal defects (VSDs, AVSDs) – the commonest lesions, which are easier to identify and although important, are not normally life-threatening if undiagnosed in the newborn period. The implication is that more of the serious lesions are missed by ultrasound. In addition there is significant regional variation in detection rates (27%-64%) across the UK leading to an inequality in the service provision.

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[5] Abu-Harb M, Hey E, Wren C. Death in infancy from unrecognised congenital heart disease. Archives of disease in childhood 1994;71:3-7.

[6] Mellander M, Sunnegardh J. Failure to diagnose critical heart malformations in newborns before discharge - an increasing problem? Acta Paediatrica 2006;95:407-13.

[7] Brown KL, Ridout DA, Hoskote A, Verhulst L, Ricci M, Bull C. Delayed diagnosis of congenital heart disease worsens preoperative condition and outcome of surgery in neonates. Heart 2006;92:1298-302.

[8] Abu-Harb M, Wyllie J, Hey E, Richmond S, Wren C. Presentations of obstructive left heart malformations in infancy. Arch Dis Child 1994;71:F179-F183.

[9] Kuehl KS, Loffredo CA, Ferencz C. Failure to diagnose congenital heart disease in infancy. Pediatrics 1999;103(4):743-7.

[10] Chang R-KR, Gurvitz M, Rodriguez S. Missed diagnosis of critical congenital heart disease. Arch Pediatr Adolesc Med 2008;162(10):969-74.

Screening for CCHD using pulse oximetry

Pulse oximetry (PO) is a well-established, accurate, non-invasive test for objective quantification of hypoxaemia. On the basis of the rationale that clinically undetectable hypoxaemia is present, to some degree, in most CCHDs, the use of this technique as a screening method for early detection was first reported over 10 years ago [11, 12] with a number of additional studies subsequently reported. In 2005, Knowles *et al* highlighted the problems with current screening methods in a report for the HTA and concluded that PO screening was a 'promising alternative … strategy but further evaluation (was) needed to obtain more precise estimates of … performance.'[13]

In 2007, a systematic review drew attention to the difficulties in precise assessment of the true accuracy of PO screening because of small numbers of patients recruited, the low prevalence of CCHDs and methodological variations reported in the studies[14]. In 2009, a statement on behalf of the American Heart Association and The American Academy of Paediatrics, which included two further screening studies, also concluded that 'further studies in large populations and across a broad range of newborn delivery systems were needed to determine if (PO screening) should become a standard of care'.[2]

Between 2009 and 2012, several major European studies, including the UK HTA funded Pulse Ox study, were published.[15,16,17,18] These studies, which recruited over 150 000 babies in total,

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[11] Richmond S, Reay G, Abu Harb M. Routine pulse oximetry in the asymptomatic newborn. Arch Dis Child Fetal Neonatal Ed 2002; 87:F83–F88.

[12] Koppel RI, Druschel C, Carter T, et al. Effectiveness of pulse oximetry screening for congenital heart disease in asymptomatic newborns. Pediatrics 2003; 111:451–455.

[13] Knowles R, Griebsch I, Dezateux C, Brown J, Bull C, Wren C. Newborn screening for congenital heart defects: a systematic review and cost-effectiveness analysis. Health Technol Assess 2005;9(44):1-168.

[14] Thangaratinam S, Daniels JP, Ewer AK, Zamora J, Khan KS. The accuracy of Pulse Oximetry in Screening for Congenital Heart Disease in Asymptomatic Newborns: A Systematic Review. Arch Dis Child 2007; 2007;92:F176-80.

[15] de-Wahl Granelli A, Wennergren M, Sandberg K, et al. Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39 821 newborns. BMJ 2009; 338:a3037.

[16] Riede FT, Worner C, Dahnert I, et al. Effectiveness of neonatal pulse oximetry screening for detection of critical congenital heart disease in daily clinical routine: results from a prospective multicenter study. Eur J Pediatr 2010; 169:975–981.

[17] Ewer AK, Middleton LJ, Furmston AT, et al. Pulse oximetry as a screening test for congenital heart defects in newborn infants (Pulse Ox): a test accuracy study. Lancet 2011; 378:785–794.

[18] Turska Kmiec´ A, Borszewska Kornacka MK, Błaz˙ W, et al. Early screening for critical congenital heart defects in asymptomatic newborns in Mazovia province: experience of the POLKARD pulse oximetry programme 2006–2008 in Poland. Kardiologia Polska 2012; 70:370–376.

all reported similar test accuracy findings and a further meta analysis and systematic review of all available studies in 2012 confirmed that PO screening was a moderately sensitive (76%) highly specific (99.9%) test for CCHD which fulfilled the criteria for screening.[19] The addition of PO screening to existing screening methods (antenatal US and postnatal examination) consistently increased detection rates of CCHD to 92-96%. The false positive rate was 0.15% but there was variability in FP rate depending on the timing of the screening (FP rate was higher if screening was performed earlier i.e. within 24 hours after birth). However a consistent finding in all studies was that between 30 and 80% of FPs had significant non-cardiac disease (such as congenital pneumonia, early onset sepsis and pulmonary hypertension) or non-critical CHD which was considered and important additional benefit of screening.[19]

The Pulse Ox study also analysed health economics[1, 20] and acceptability of screening to both parents and clinical staff [1, 21] and confirmed that PO screening was both cost-effective in a NHS setting, and acceptable to parents and staff. Importantly, anxiety in mothers of those babies who tested false positive, was not increased compared with the test negative cohort.[21] In 2014, the largest PO screening study to date, reported test accuracy from a cohort of over 120 000 babies in China.[22] The findings were similar to the previous European studies and an accompanying editorial in the Lancet concluded that further research was unnecessary and that routine implementation should be considered.[23]

In Jan 2011, the evidence from the Pulse Ox study[17] and Granelli's Swedish study[15] were considered by the USA SACHDNC who decided there was sufficient evidence to introduce routine PO screening.[24] By the end of 2015 approximately 90% of all babies born in the US underwent testing. PO screening has also been recommended in Switzerland, Poland, Ireland and Norway.[25] In the UK a survey in 2012 indicated that approximately 20% of UK maternity units had independently introduced PO screening but there was a wide variation in the protocol

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[19] Thangaratinam S, Brown K, Zamora J, et al. Pulse oximetry screening for critical congenital heart defects (CCHD) in asymptomatic newborns: a systematic review and meta-analysis. Lancet 2012; 379:2459–2464.

[20] Powell R, Pattison HM, Bhoyar A, et al. Pulse oximetry as a screening test for congenital heart defects in newborn infants: an evaluation of acceptability to mothers. Arch Dis Child 2013; 98:F59–F63.

[21] Roberts TE, Barton P, Auguste P, et al. Pulse oximetry as a screening test for congenital heart disease in newborn infants: a cost effectiveness analysis. Arch Dis Child 2012; 97:221–226.

[22] Qu-ming Zhao , Xiao-jing Ma, Xiao-ling Ge *et al*. Pulse oximetry with clinical assessment to screen for congenital heart disease in China: a prospective study. Lancet 2014; 384:747–754.

[23] Ewer AK. Pulse oximetry screening: do we have enough evidence now? Lancet 2014;384:725-6.

[24] Kemper AR, Mahle WT, Martin GR, et al. Strategies for implementing screening for critical congenital heart disease. Pediatrics 2011; 128:e1259–e1267.

[25] Ewer AK. Review of pulse oximetry screening for critical congenital heart defects. Current Opinions in Cardiology 2013;28:92-6.

employed. Seventy percent of units who were not screening were interested in introducing the test but required further guidance.[26]

In 2013 the UK National Screening Committee initiated a national consultation on PO screening and following this, and the publication of further data from the UK,[27] in May 2014, decided that a feasibility pilot study was required in order to understand the effect of PO screening on clinical services.

Aims of the newborn pulse oximetry screening pilot

The aims of the newborn PO screening pilot:

- to evaluate the feasibility of implementing newborn PO screening on NHS services
- to establish the effect on clinical services when PO screening is undertaken as part of the newborn and infant physical examination NIPE Programme.

Governance

A Pilot Project Board was convened in September 2014 (chaired by Dr Anne Mackie) and met regularly throughout the pilot period to oversee the project. Membership of the Board was made up of NIPE Programme staff, a consultant neonatologist, a consultant paediatrician, midwife and neonatal nurse, service users and clinical research fellows. The Terms of Reference for the Newborn Pulse Oximetry Pilot Board and Board membership is attached as Appendix 2.

The project was led by Newborn PO Screening Pilot Lead, Claire Evans and NIPE Programme Manager Jill Walker. Regular board and work stream meetings meant that tight project management processes were employed.

Trust selection

Trusts who had actively expressed an interest in the pilot were approached. Others with specific service features were selected from the original UK NSC consultation report from those Trusts that had expressed an interest in participating in any future pilot work. In order to ensure a sufficiently large cohort and to understand issues relating to provision of newborn PO

[26] Singh A, Ewer AK. Pulse oximetry screening for critical congenital heart defects: a UK national survey. Lancet 2013; 381:535.

[27] Singh AS, Rasiah SV, Ewer AK. The impact of routine pre-discharge pulse oximetry screening in a regional neonatal unit. Arch Dis Child Fetal and Neonatal Ed 2014; 99:F297-F302.

screening in large and small Trusts, it was important to include those with higher and lower delivery rates and different service level characteristics.

The 15 participating Trusts were selected to ensure a cross-representation of Tertiary referral, District General and Midwifery-led maternity service provision and to represent a wide spread of size and annual birth-rates. The list of participating trusts is provided in Appendix 3

Letters were sent out to Trusts to confirm their formal organisational agreement to participate in the pilot project and to identify a lead contact.

For the purposes of the pilot and to ensure data analysis which showed different levels of feasibility and impact, participating Trusts were sub-grouped into two groups. The reasons for two groups was to address the requirement to assess the ability of those trusts already undertaking PO screening to change from their existing local pathway to the pilot screening pathway and any practice or workload implications. Those trusts not already performing PO would implement both PO and the screening pathway. The impact on work practices and workload would be evaluated.

- Group A (Trusts already performing pre-discharge newborn PO screening who would be aligning their existing PO pathway to the agreed national pilot pathway (see page 18) from 1st July 2015). There were seven trusts in this group
- Group B (Trusts not currently offering pre-discharge newborn PO screening who would be implementing the agreed national pilot pathway as a new screen from 1st July 2015). There were eight trusts in this group.

Stakeholder engagement

Building on initial positive communications between the pilot Project Lead and NIPE Programme Manager with consultant paediatricians and neonatologists at potential participating Trusts, informal site visits with Trust Pilot Clinical Leads took place in January and February 2015. These meetings were extremely useful in understanding the Trusts' positions, current and proposed service delivery models and in informing development of the Phase 1 data set and baseline questionnaire.

Formal wider stakeholder meetings then took place at participating Trusts throughout March and April 2015 with pilot Board representation including Claire Evans (Pilot Project Lead), Jill Walker (NIPE Programme Manager), Professor Andrew Ewer (PO Advisor to the programme) and Dr Matthew Cawsey (Clinical Research Fellow).

These meetings provided an opportunity to offer further information to a wider stakeholder audience, to outline the project, showcase the developed clinical resources and answer particular queries. Building on the valuable on-going informal communications, these meetings

also promoted and highlighted the aims and objectives of the pilot to those with strategic influence at Trust level as well as those delivering the day-to-day NIPE screening service and were considered to be a key element of the pilot methodology.

A PO Screening Pilot Workshop for participant Trust representatives was held in October 2015 as a pilot process feedback mechanism. The aim of this event was to share preliminary data findings with attendees, gain feedback on pilot participation experiences and the use of NIPE SMART PO screens. It also provided an opportunity for valuable networking amongst the pilot Clinical Leads. The event was attended by 25 staff from the pilot Trusts including pilot Clinical Leads, screening coordinators and data reporters.

Funding

Central funding was made available on a pro rata basis to support local data collection and provision of equipment (pulse oximeters and reusable probes). Each participating Trust received allocations based on birth rate and arrangements were formalised via two-way agreements between each Trust and Public Health England (PHE).

Public Engagement

Updates about the pilot progress were posted on the NIPE programme web page on the Public Health England (PHE) Screening Blog for public access:

https://phescreening.blog.gov.uk/2015/07/30/newborn-pulse-oximetry-screening-pilot-under-way/

http://webarchive.nationalarchives.gov.uk/20150408175925/http://newbornphysical.screening.nhs.uk/pulseoximetry

Aims and objectives of the newborn PO screening pilot

Proposed objectives for the pilot

The proposed objectives for a newborn PO pilot were discussed at the UK NSC meeting on 12th March 2014. The following table describes the suggested UK NSC achievable pilot objectives within the proposed pilot design and timeframe:

Table 4: Objectives specified by the UK NSC

Newborn PO screening
• to collect data to assess current service provision and impact of the introduction of PO as a new screening strategy • establish routine data systems (and/or routine data linkage, e.g. between screening programmes) for audit, quality assurance and monitoring of longer term outcomes • to define optimal test procedures for pre- and post-ductal saturation measurement (PO screening) and newborn clinical examination (including timing, number of repetitions and the temporal relationship between PO and clinical examination) • to clarify and test pathways for referral for further investigations after a screen positive result (including cardiac and non-cardiac causes) • to develop both antenatal and postnatal information for parents and health professionals • to institute training for health care professionals involved in newborn screening using PO as a new screening test

The agreed aims of the newborn PO screening pilot are to evaluate the feasibility of implementing newborn PO screening on NHS services and to establish the effect on clinical services when PO screening is undertaken as part of the newborn and infant physical examination NIPE Programme.

The objectives of the pilot as agreed by the pilot Project Board:

- to identify existing PO screening pathways already in use within the defined participating Trusts
- to describe the variation between the maternity services within a defined number of Trusts in respect to clinical workload, protocols and resources associated with existing routine PO screening carried out on newborns.
- to describe the variation between those Trusts in respect to clinical workload, and resources associated with implementing routine PO screening as a new screening test carried out on newborns
- to audit screening outcomes in all eligible babies: all cardiac diagnoses, non-cardiac diagnoses in screen positive babies, referrals after a positive cardiovascular screen following NIPE or PO, deaths within 1 month of birth, through the collection of data and analysis
- support implementation of training for health care professionals involved in newborn screening using PO in the pilot.
- develop information for parents and resource media for health professionals to be used in the pilot

It was important to understand from the pilot, the impact on clinical service delivery within the defined two pilot Trust groups of either changing to the newborn PO pilot screening pathway (see Figure PO1) or implementing PO screening as a new screening test. The objectives of the pilot would enable the assimilation of this information and would inform the overall evaluation of a feasible model for implementing PO screening. It was of particular interest to understand the specific implications in relation to staff workload and any required reconfiguration of clinical services or realignment of staff roles and responsibilities as a result of implementation of the pilot screening pathway.

Objectives not in the scope of the pilot

There are objectives that are not in scope of the pilot but may inform research activity in the future. The pilot with a restricted sample size and timeframe would be unable to evaluate reductions in mortality from cardiac causes in the first year of life resulting from enhanced NIPE screening with PO. However, a pilot could confirm previous work on test accuracy of PO for diagnosing life-threatening CCHDs and non-cardiac causes of hypoxaemia as well as determine the workload, resources, and clinical referral pathways required in a non-research population-based programme. Moreover, the pilot could establish the methodologies for tracking outcomes to one year that would allow monitoring of CHD deaths and surgical outcomes, including after false negative or false positive results. This would inform any future larger scale population-based trial but is not within the scope of the pilot.

The primary outcome for newborn screening for CHDs is a reduction in pre-diagnosis collapse and death from CCHDs. This could be measured at the end of the first year of life as up to 20% of children born with major or serious CHDs (approx. 2 per 1000 live-births) will die in the first year of life. To evaluate this outcome would require a follow-up of all babies to one year of age and a large sample size. This would only be feasible within a whole population cluster-randomised clinical trial undertaken over 1-3 years.

Target outcomes of newborn PO screening pilot

In order to fully evaluate the performance of the screening programme in detecting all structural CHD, the outcomes to be monitored prospectively before and after the introduction of PO in pilot sites included:

- Cardiac diagnoses (all structural cardiac diagnoses)
- Non-cardiac diagnoses – all diagnoses with hypoxaemia noted before discharge (including at screen) or on readmission (if within 24 hours after birth)
- Deaths within 30 days of birth.

Primary targets of screening

The primary outcome for an evaluation of the test accuracy of PO screening is timely diagnosis, defined earlier as diagnosis of a life-threatening CCHD before collapse or death occurs. Earlier detection prior to collapse results in improved survival and outcomes after surgery.[28] Children with non-critical CHDs that do not necessarily lead to preoperative clinical deterioration may also benefit from earlier detection as this allows parents and clinicians to fully discuss and prepare a management plan. However there is currently insufficient evidence to suggest that earlier detection influences the outcomes of surgery in these children.

Table 5 below indicates how the definition of cardiac diagnoses likely to benefit from screening has been operationalised in different studies.

Table 5: CHDs targeted by newborn PO screening

Primary target of screening: Children with the following types of CHD are most likely to benefit from screening			
LIFE-THREATENING CHDs (Health Technology Assessment review) Knowles, et al. 2005	**CRITICAL CHD (Pulse Ox Study/ Health Technology Assessment)** Ewer, et al. 2012	**CRITICAL CHD (Systematic review and meta-analysis of 12 PO studies)** Prudhoe, et al. 2012	**CHDs OPERATED IN FIRST 30 DAYS OF LIFE (NICOR national cardiac surgical audit)**[25]
Defined as: *CHDs that are likely to lead to collapse in newborns*: ▪ TGA: transposition of the great arteries ▪ HLH (incl. mitral and aortic atresia) ▪ PA: pulmonary atresia ▪ IAA: interrupted aortic arch ▪ AS: aortic stenosis (critical) ▪ TAPVC: total anomalous pulmonary venous connection ▪ COA: coarctation (severe)	**Defined as:** *CHDs from the following groups regardless of timing of surgery:* ▪ HLH ▪ PA with intact ventricular septum ▪ TGA ▪ IAA *AND infants dying/needing surgery within 28 days of birth with* ▪ COA: coarctation ▪ AS: aortic stenosis ▪ TOF: tetralogy of Fallot ▪ PA with ventricular septal defect (VSD) ▪ TAPVC: total anomalous pulmonary venous connection ▪ PS: pulmonary stenosis	**Defined as:** *CHDs from the following groups regardless of timing of surgery:* ▪ HLH ▪ PA with intact ventricular septum ▪ TGA ▪ IAA *AND infants dying/needing surgery within 28 days of birth with* ▪ COA: coarctation ▪ AS: aortic stenosis ▪ TOF: tetralogy of Fallot ▪ PA with ventricular septal defect (VSD) ▪ TAPVC: total anomalous pulmonary venous connection *(NB excludes pulmonary stenosis)*	**Defined as:** *CHD groups in which >50% of those operated were operated aged 30 days or less:* ▪ HLH (incl. mitral and aortic atresia) ▪ Single ventricle (incl. tricuspid atresia, double inlet ventricle) ▪ IAA: interrupted aortic arch ▪ TAPVC: total anomalous pulmonary venous connection ▪ TGA: transposition of the great arteries ▪ CAT: truncus arteriosus (common arterial trunk) ▪ COA: coarctation

All these sources agree that the following CHDs are key targets of screening:

- HLH/single ventricle
- PA (with IVS)
- TGA
- IAA

The following defects also have the potential to lead to collapse and subsequent worse outcomes after surgery and should also be targeted by screening:

- TAPVC
- COA
- AS
- TOF

Although the less severe forms of PA (with VSD), COA, AS, TOF and TAPVC may not lead to collapse, there is no objective test to predict at the time of screening or diagnosis which children with these conditions will collapse and which will not.[28]

Ewer and Prudhoe's established a post-hoc definition of *'critical CHD'*, based on surgical decision-making, which additionally included some PA (with VSD), COA, AS, TOF and TAPVC as screening targets, however there are some limitations and possible biases to this as the number of children falling into this category may not be comparable over time as clinical practice alters. As it is unlikely that many surgeons delay a procedure significantly once a CHD diagnosis is made, children with a CHD diagnosed before 28 days have a higher chance of a 'true positive' than a 'false positive' designation, even if collapse is relatively rare such as in a case of TOF, whereas any child who is diagnosed after 28 days will always be deemed 'not critical' and therefore a 'true negative' even if they subsequently collapse.

As the aim of this pilot is to determine the workload associated with positive screen results using PO, it would be appropriate to record the detection of all CHDs. The proposed target lesions for screening (HLH, PA, TGA, IAA, TAPVC, COA, AS and TOF) are those which have the potential to collapse, we will also collect data on the timing of surgery so that the outcomes of the pilot can also be appraised in terms of 'critical' CHD.

[28] Ewer *et al* and Prudhoe *et al* used the timing of surgery as a marker of severity or potential for collapse whereas Knowles *et al* based the probability of collapse on published evidence and expert review.

Newborn PO screening pilot methodology and methods

The aim of the newborn PO screening pilot was to evaluate the feasibility of implementing newborn PO screening on NHS services and establish the impact on clinical services when PO is undertaken as part of the newborn and infant physical examination NIPE Programme. This section outlines the methodology and methods used for the pilot.

Methodology

The Pilot data collection was conducted over two phased intervals:

Phase 1 - retrospective data collection and submission of baseline demographic data and service delivery model questionnaire responses took place between end February and mid-May 2015.

Pre-phase 2 prospective data collection took place in June 2015.

Phase 2 - commencement of newborn PO screening (as a new screen or alignment with national screening pathway) with concurrent prospective data collection from 1st July 2015.

Newborn PO Pilot Screening Pathway
A PO screening clinical pathway was developed as a benchmark for clinical practice (a modified version of the Pulse Ox pathway [see introduction])) and ratified by the NPOSP Board. This was disseminated to participating Trusts for use across all pilot sites (see page 26).

Data Collection Process
Considerable work was undertaken to develop and refine baseline questionnaire data and retrospective and prospective datasets.

Submissions

- Phase 1 data and questionnaire responses were submitted via the PHE Select Survey tool
- Pre-Phase 2 and Phase 2 screen positive data was submitted via a standardised Pilot submission tool (Excel spread sheet) based on the agreed dataset. A substantial amount of work was undertaken to agree and finalise the Phase 2 prospective dataset to ensure appropriate and streamlined questions in a user-friendly format
- Trusts were supported in data collection for Phase 2 by the pilot Project Lead and Clinical Research Fellow.

Phase pilot objectives

Phase 1: February – April 2015

In Trusts in which newborn PO screening is already undertaken (Group A):

- to describe the variation between units with respect to clinical workload, protocols and resources associated with existing routine PO screening carried out on newborns
- to identify whether standard protocols are already in use and suitable for implementation in new screening sites; to recommend a standard protocol for screening and clinical referral pathways to be implemented in Phase 2
- to audit screening results in eligible babies: all cardiac diagnoses, non-cardiac diagnoses with hypoxaemia, referrals after positive screen on NIPE/PO, deaths within 1 month of birth.

In units which agree to implement newborn PO screening as a new test (Group B):

- collect baseline data before implementation of newborn PO screening including:
  - new local data collection by staff within the unit
  - establishing data extraction from routine data systems (and/or routine data linkage) for audit, quality assurance and monitoring of longer term outcomes
- develop information for parents and resource media for health professionals to be used in the pilot
- implement training for health care professionals involved in newborn screening using PO in the pilot.

Phase 2: July-December 2015

In Trusts in which newborn PO screening is already undertaken (Group A):

- baseline prospective data collection prior to implementation of the Screening Pathway
- to implement /align current practice with the agreed newborn PO screening pathway
- to estimate the workload and resources associated with introducing the aligned pathway
- assess impact on screening and referral services.

In Trusts which are implementing PO screening as a new test (Group B):

- baseline prospective data collection prior to implementation of the agreed newborn PO screening pathway
- to evaluate the impact upon clinical workload and resources associated with introducing a new programme of enhanced NIPE screening that would include routine PO screening for newborns in Trusts in England
- to evaluate the implementation into clinical practice of a standard screening protocol and clinical referral pathways.

Ethics/governance for auditing individual outcomes

Research ethical approval was not required for service evaluation and audit, but analysis of individual data outside the clinical care team (or linkage) would require Section 251 approval under Schedule 3 (PHE) or Schedule 5: http://www.hra.nhs.uk/documents/2013/08/cag-pre-application-decision-tool.pdf.

Recording outcomes of newborn screening during the pilot

Phase 1

A retrospective dataset was requested from participating Trusts. Each was invited to provide six months of aggregated data i.e. group numbers as per dataset. No patient identifiers were requested or required. This provided a summary of patient numbers and workload but it would not be possible to interrogate such data further to understand screening pathways, test performance or outcomes for individual babies.

Phase 2

A ‘baseline’ prospective dataset was collected within each Trust for one month prior to the introduction or alignment of the newborn PO pilot screening pathway. The aim was to offer an immediate, direct pre-pilot comparison. Each screen positive case was tracked through the dataset required elements; however, these data are of limited value as the data were inconclusive due to the short data collection period.

Phase 2 prospective data collection involved collation of screening results from the eligible population. In addition each screen positive case was reported as per dataset in order to provide information about workload and resources required to achieve a diagnostic outcome.

Identifiable data for individual babies was not collected as part of the pilot, however Trusts were asked to maintain a record of the NHS numbers of all babies screened during Phase 2 to inform future research activity if required. In particular, a data linkage

study could evaluate the feasibility of tracking individual outcomes of babies screened in other databases to enumerate antenatal diagnoses, deaths, readmissions, and cardiac interventions.

Methods

Group A: Survey of existing routine screening in maternity services

Phase 1 only: Commenced February 2015

- 7 Trusts identified (who had previously expressed an interest in participating in the pilot) with sufficient variation in population/unit characteristics – choice of units enabled assessment of whether significant differences in PO implementation are likely due to specific unit characteristics, e.g.:
    - midwife-led/obstetric care provision (availability of medical advice or geographically-isolated midwifery led unit)
    - rural/urban
    - established/ recent programme
    - DGH/tertiary
    - echocardiogram on-site/off-site
    - differences in newborn PO screening protocols (e.g. discharged home before NIPE).
    - provision of NIPE screen if not performed prior to discharge

- **Describe screening pathways, including:**
    - screen coverage and exclusions
    - screening protocol – time, pre- and post-ductal site, relation to NIPE or clinical examination, number of repeats
    - designations of staff who undertake newborn PO screening
    - staff training – describe current training, who provides the training, resources used and assessment of competency
    - equipment requirement – oximeter used make and model, consumables used

- **Describe initial clinical referral pathways, including:**
    - initial clinical referral and diagnostic resources –Neonatal Unit , echo referrals, transfer, urgent retrieval, non-cardiac investigations

- **Describe outcomes (endpoints of screening pathway), including:**
  - symptomatic babies identified at time of screening – subsequent referral and management
  - referrals after PO screen positive – subsequent referral and management
  - referrals after NIPE screen positive – subsequent referral and management
  - admissions – within first month after birth
  - cardiac diagnoses – all; any surgery and timing of surgery
  - non-cardiac diagnoses – detected at PO/NIPE – results of referral.

Group B: Implementing routine PO screening in maternity services not currently using this test

Phase 1: February 2015 – to monitor workload, resource use and outcomes before implementation of PO screening

- Identify Trusts that were willing to implement PO screening and ideally currently use NIPE SMART (or implementation imminent) – record basic information:
  - population characteristics, annual births, staff complement, etc.
  - staff training given
  - equipment provided
  - current referral pathways for suspected cardiac and other diagnoses after NIPE
  - validate NIPE SMART recording

- **Record data items collected in Group B Trusts including:**
  - antenatal diagnoses
  - coverage and exclusions from screening
  - symptomatic babies identified before screening – subsequent referral and management
  - referrals after NIPE screen positive – subsequent referral and management
  - admissions – within first month after birth
  - cardiac diagnoses – all; any surgery and timing of surgery
  - non-cardiac diagnoses – detected through NIPE – results of referral

Phase 2: June to December 2015 – to monitor workload, resource use and outcomes

Before and after implementation of PO screening

- Record data items (as above) and in addition:
  - referrals after PO screen positive – subsequent investigations, referral and management

- non-cardiac diagnoses – detected through PO – investigations, results of referral.
- prospective ‘baseline’ data collection prior to implementation of screening pathway and after implementation.

Target outcomes (as for Group A) are:

1. Cardiac diagnosis (all structural cardiac diagnoses) – with information whether they were operated by 30 days of age or not.
2. Non-cardiac diagnosis – all diagnoses with hypoxaemia noted before discharge (including at screen) or on readmission (if within 24 hours of birth). The timeframe for readmission might be 30 days as with cardiac diagnoses, however only those readmitted with hypoxaemia within 24 hours might be considered a ‘missed’ diagnosis.
3. Deaths within 30 days of birth.

Data Collection

The data for each pilot phase was collated by varied data collection tools as follows:

- online questionnaires for recording data – de-identified data was submitted via an online questionnaire (or spread sheet) to the PHE ‘Select Survey’ central database for analysis.
- Excel spread sheet completion with defined dataset
- NIPE SMART IT system.

Data analysis Phase 1

Data analysis involved:

1. An overall description of the protocols, workload and resource use in maternity units using PO screening
2. An appraisal of the feasibility of outcome measurement
3. Recommendations for the design of Phase 2.

Data analysis Phase 2

Data analysis involved a comparison of

1. Workload, training and resource requirements in participating pilot Trusts implementing PO as a new screening test (comparator to pre-screening position)
2. Evaluation of test performance and screening outcomes
3. Recommendations for future research.

Newborn PO screening pilot methodology summary

Table 6 provides a summary of the pilot methodology and methods. The table details the data collation from both pilot groups in Phase 1 of the pilot. Phase 1 of the pilot

involved process mapping across all the pilot trusts in both groups collating data on the organisational profiles, NIPE examination service provision, processes for PO screen positive case processes in Group A and cardiac referral processes in Groups A and B.

Phase 2 of the pilot for Group A involved the alignment to the pilot screening pathway. The Group B Trusts commenced PO screening as a new screening test. The impact of change on clinical services and workload for both Groups was assessed in Phase 2 through data collation and the outcome management of the PO screen positive cases.

Table 6: Summary of the pilot methodology

<table>
<tr><td rowspan="4">Phase 1
(Feb 2015)

Pre implementation Phase 2
(June 15)</td><td colspan="2">Newborn PO Screening Pilot Methodology:
Predefined newborn population
Letter to participating Trusts to secure service agreement to participate in Pilot</td></tr>
<tr><td>Group A:
Trusts performing newborn PO prior to Pilot</td><td>Group B:
Trusts not performing newborn PO prior to Pilot</td></tr>
<tr><td>Process mapping implementation with all participating Trusts in Group A: (Electronic predefined questionnaire)
Data collation and analysis of following:
Organisational profile
Current service provision processes for the NIPE examination
Current service provision processes for screen positive PO cases including protocol and resources used.
Dataset for retrospective collation of outcome measurements for screen positive PO cases.
Recommendations from Phase 1 to inform Phase 2</td><td>Process mapping implementation with all participating Trusts in Group B: (Electronic predefined questionnaire)
Data collation and analysis of following:
Organisational profile
Current service provision processes for the NIPE examination
Current service provision processes for cardiac referrals including resources used.
Recommendations from Phase 1 to inform Phase 2</td></tr>
<tr><td>Group A</td><td>Group B</td></tr>
<tr><td>Pre screening pathway implementation prospective data collection</td><td>Pre screening pathway implementation prospective data collection</td></tr>
</table>

Phase 2 **(July- Dec'15)**	Introduction of the newborn PO pilot screening pathway. Collation of comparative data for evaluation of impact of pilot screening pathway upon existing service provision. Use of predefined dataset	Introduction of the newborn PO pilot screening pathway. Collation of comparative data for evaluation of impact of commencing PO as a new screening test upon existing service provision. Use of predefined dataset

Newborn PO Screening Pilot Data Management Group

A Newborn PO Screening Pilot Data Management Group was established in May 2015 in Phase 1 of the pilot. The aims of the Group were to ensure the safe storage and management of all data collection and collection tools during the pilot and compliance with PHE policies for information governance, data transfer and storage. The Group met monthly throughout the Phase 2 implementation Pilot period. The Terms of Reference for the Group are attached as Appendix 6.

Meeting agenda items included regular reviews of the data reporting in terms of report type development by Northgate Public Services (UK) NPS. Data submissions were monitored and reviewed in respect to both Phase 1 and 2 along with data analysis updates. Strategies were developed to minimise outliers with outstanding data submissions.

Risk management and IT governance updates were provided by the IT Specialist. The pilot was registered on the Public Health England (PHE) Information Asset Register and a RAG status assigned for risk and controls to mitigate risk. The pilot data flow diagram is attached as Appendix 12.

NIPE SMART PO fields development

A key objective of the pilot was to establish routine data systems for audit, quality assurance and monitoring of longer term outcomes. The NIPE SMART was already well established nationally as an IT system to capture the NIPE examination coverage and screening outcomes. It was agreed by the pilot Project Board that the existing rudimentary NIPE SMART PO data would be further developed for pilot use.

Work was undertaken between the pilot Project Team (led by the Pilot Project Lead) and Northgate Public Services (UK) Limited (NPS) to support the PO screening pathway and

incorporate sustainable data fields into NIPE SMART (Screening Management and Reporting Tool) in line with the developed specification. Work included:

- development of new PO fields, screening outcome pathways, pre-defined searches and search capabilities as well as screen design, system functionality and local and national reporting functionality in a two-phased approach to releasing the software
- user-acceptability testing (UAT) of NIPE SMART PO functionality took place throughout the development phases and versions of the functionality in April and July 2015
- new fields were commissioned, integrated into NIPE SMART and ready for use prior to commencement of Phase 2 and further developments were subsequently made to include the reporting functionality.

This work was undertaken in a systematic and timely manner, meeting critical deadlines and using effective collaborative project management processes.

Prior to commencement of Phase 1 of the Pilot, 8/15 Trusts had gone live with the NIPE SMART system and as a result of considerable effort 6 more Trusts went live prior to, or soon after, commencement of Phase 2. One Trust did not engage with NIPE SMART. This Trust however utilised Pilot funding provided for data clerk function and extrapolated data in line with pilot data submission requirements. To enable the non-NIPE SMART Trust to submit parallel data the data fields were provided by NPS to enable the programming of many of the data fields to the hospital information system (HIS) of this Trust. However, not all of the data fields could be replicated by the Trust's HIS.

Success criteria for the NIPE SMART PO field development

The development of the PO fields within the existing NIPE SMART system were designed as a tool that supported robust, consistent and complete data collection using a standard dataset and validation rules for Phase 2 of the pilot. The expected benefits of using NIPE SMART as a data collection tool also included the provision of data to support the newborn PO screening pathway in terms of efficacy and facilitation of the robust capture of coverage. The NIPE SMART system also provided data so that a more detailed analysis of screen positive outcomes could be undertaken.

As part of the IT workstream for the NIPE SMART PO screen development it was necessary to establish success criteria for the implementation of the new fields in relation to the pilot requirements:

Success Criteria objectives:

- efficacy of the new NIPE SMART PO screen content mapped directly to the newborn PO screening pathway
- development of the screen content required to capture the PO screening data
- design, development and scheduling for reporting capabilities
- training Needs Analysis for the provision of a programme of WebEx demonstrations in the use of the new PO screens to support the pilot Trusts
- establishment of feedback mechanisms
- performance evaluation of the NIPE SMART PO fields in supporting the newborn PO screening pilot .

Measurable outcome parameters

It was essential that the coverage demographic information be estimated in order to identify the data denominators. The estimated numbers of eligible babies to be screened as part of the pilot were aggregated from the annual birth rate for the length of the pilot from all 15 participating pilot Trusts and the projected number of screen positive cases.

The following data items in Table 7 were identified as denominator data to capture the eligible cohort overall screening activity:

Table 7: Screening activity reporting

Reporting	Rationale
Type of report	3 different reports provided to the Pilot Trusts: • local PO activity report for each individual Trust • national summary data report –cumulative pilot data from 1st July – 31st December 2015 (Phase 2 implementation) • anonymised national activity from each pilot Trust report (provided in latter period of pilot)
Report scheduling	The frequency of reports determined: • weekly summary report to NIPE Programme Centre (Project Lead) • weekly summary report to Pilot Trusts in first 2 months of Phase 2 to enable Trusts to monitor their screening activity • fortnightly reports until the end of Phase 2 (31/12/16) • fortnightly activity report to NIPE Programme Centre (Project Lead)
Distribution	Designated person (Project Lead and Project Support) to distribute the reports to the pilot Trusts.
Local activity report – reporting items	• summary of local screening outcomes • coverage mapped to screening outcomes • coverage – weekly breakdown • screening outcomes • positive screens (included NIPE SMART confidential ID numbers

	to assist Trusts with case identification for data submissions) • practitioner activity • definitions

The rationale for the provision of detailed reports to the pilot Trusts was to supplement the search and pre-defined search functionality during the pilot phase and enable further breakdown of the local summary data, management of the local screening cohort and ability to monitor and action any issues arising from the PO screening at service level.

NIPE SMART user feedback mechanisms

Following development and implementation it was necessary to establish feedback mechanisms for the users of the new NIPE SMART PO fields. During the pre-pilot stage (April-May 2015) two Trusts tested the new PO screens and provided feedback on a weekly basis. Both Trusts had been using NIPE SMART for some time prior to participating in the pilot. This level of user feedback was crucial prior to the live release of the new screens in Phase 2 of the pilot. Collated feedback was obtained throughout the period of Phase 2 of the pilot through the NIPE helpdesk facility for issues that arose requiring the assistance of the helpdesk. The frequency of the problems was understandably greater at the beginning of Phase 2 than in the final stages of the pilot.

To minimise clinician disruption and time whilst trying to maximise convenience, WebEx and teleconferencing media were selected and delivered as the optimum training approach for demonstrating the new screen layout and content to the pilot Trusts. The sessions were facilitated by the Northgate Consultant for the pilot and the Pilot Project Lead. This provided an additional opportunity for user feedback to be gained. Key representatives from the Trusts would then undertake cascade training locally as per the local training needs analysis as part of the PO screening implementation. A total of twelve out of the fourteen pilot Trusts with NIPE SMART participated in the WebEx demonstration schedule. The two Trusts that did not participate were in Group A and B respectively.

Lastly, feedback was obtained from the Pilot Workshop event (October 2015) which brought all the Pilot Clinical Leads and screening representatives from the pilot Trusts together. The NIPE SMART feedback session was delivered in an interactive way to allow for discussion and comment from the attendees. In addition the pilot Trusts were provided with a proforma to submit additional comments on the user ability and functionality of the new screens. These comments and suggestions have all been documented and reviewed to further enhance the feedback process.

Project management of NIPE SMART PO screen development

The scope, approach and delivery methodology of the NIPE SMART PO project was defined within the Project Initiation Document (PID), attached as Appendix 5.
The 'Agile' methodology underpinned by a consultative engagement approach was used by NPS to define requirements. The process ensured that key stakeholders agreed the contents of the releases and supporting development and testing documents were produced by NPS at the beginning of the NIPE SMART PO screens project.

Highlight reports were provided by NPS on a monthly basis throughout the pilot period and subsequently presented at each Pilot Project Board.

Pilot review meetings via teleconference media took place between the NPS Project team, the Pilot Project Lead and NIPE Programme Manager on a weekly basis during the acute phase of the screen development transitioning to biweekly towards the end of the Pilot. The aim of the review meetings was to plan, assess, implement and evaluate the new PO data fields' development and discuss and action any issues that arose at local Trust level throughout the period of the pilot. Additional members from the Pilot Project Board contributed to the meetings as and when necessary particularly with the design and content of the data fields.

Conclusions from the success criteria objectives

To conclude this section the following key findings measure the success of the criteria objectives set within the context of the pilot objective for establishment of routine data systems:

- The 'eligible for screening' population cohort was large enough to measure the outcome and impact of the introduction of newborn PO screening overall.
- The 'user acceptability testing' (UAT) process of the PO screens was conducted in a timely manner allowing for the new releases to the live NIPE SMART system as scheduled in accordance with the PID.
- The frequency of the reports and level of data delivered throughout the pilot period was sufficient for data analysis purposes served the monitoring and management purposes of the cohort data both for the pilot data collation and participating Trusts.
- The utilised feedback mechanisms were sufficient and effective in capturing the feedback required. Specific issues in relation to the functionality of the PO fields where identified by Trusts that could inform future releases and the long term sustainability of the data fields. Trust issues are discussed in a more contextual basis in other chapters within this document.

- The use of WebEx and teleconference media to demonstrate the new PO data fields was well received by the pilot Trusts and positive feedback received pertinent to the design and content of the data fields. The media of choice negated the need for clinical staff to attend training on the new screens at an external source therefore maximising the WebEx participation and confirming the relevance of the use of such media to provide training. The two Trusts that did not engage with the demonstration schedule did not report any issues with the new screens.

- Overall the positive working relationships, project management and communication strategy between NPS and the pilot project team proved highly effective. This ensured the development of the required data fields aligned to the pilot methodology for the purpose of pilot data collation and accurate capture of the eligible cohort population and denominator data.

Section Two

Newborn pulse oximetry screening pilot data findings

Mapped pilot objectives:

- identification of existing PO screening pathways already in use within the defined participating Trusts
- description of the variation between maternity services within a defined number of Trusts in respect to clinical workload, protocols and resources associated with existing routine PO screening carried out on newborns

The first pilot objective seeks to identify the existing PO screening pathways already in use within the defined participating trusts. The second objective relates to a description of the variation between the maternity services within a defined number of trusts in respect to clinical workload, protocols and resources associated with existing routine PO screening carried out on newborns. The Phase 1 questionnaire and retrospective data collection was designed to capture the data required to inform both objectives.

The Phase 1 questionnaire data findings inform the first two pilot objectives.

Phases 1 and 2 of the pilot required the collection and reporting of data by all the pilot trusts. Phase 1 involved the completion of an electronic questionnaire and the submission of a completed Excel spreadsheet dataset for retrospective data over a defined six month period. There was successful collection of data from the questionnaire following completion by all the pilot trusts and therefore available for analysis. The retrospective data collection was incomplete and could not be analysed and discussed further within this section.

The data findings section is mapped to the specific pilot objective relating to each set of findings. The Phase 1 questionnaire data findings are mapped to the pilot objective to describe the variation between maternity services within a defined number of Trusts in respect to clinical workload, protocols and resources associated with existing routine PO screening carried out on newborns. Some of the data analysis is represented through the use of descriptive statistics in graph/chart form and data tables. A synopsis of prevalent findings is provided for the data not graphically presented.

The Phase 1 questionnaire is subdivided into the following section headings:

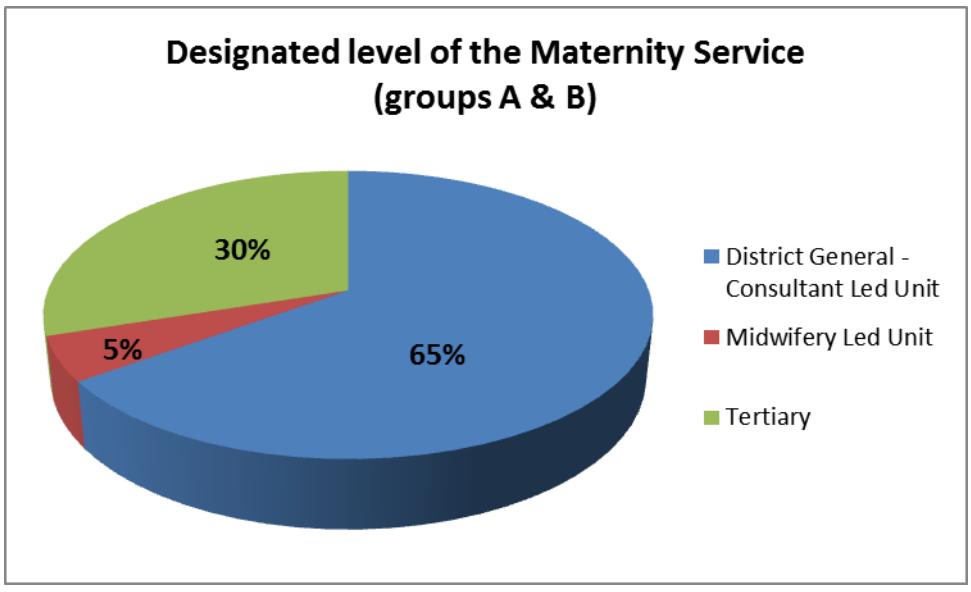
1. organisational profile (Trust characteristics and demographic data)
2. neonatal services provision
3. local newborn physical examination service provision (NIPE)
4. local newborn PO screening service provision
5. newborn PO screening thresholds (Groups A and 'targeted' PO in Group B)
6. home environment and midwifery-led unit service provision
7. local paediatric cardiac referral processes
8. education and training

The data findings from the Phase 1 questionnaires will be reported in the order of the section headings.

Pilot Trusts organisational profile

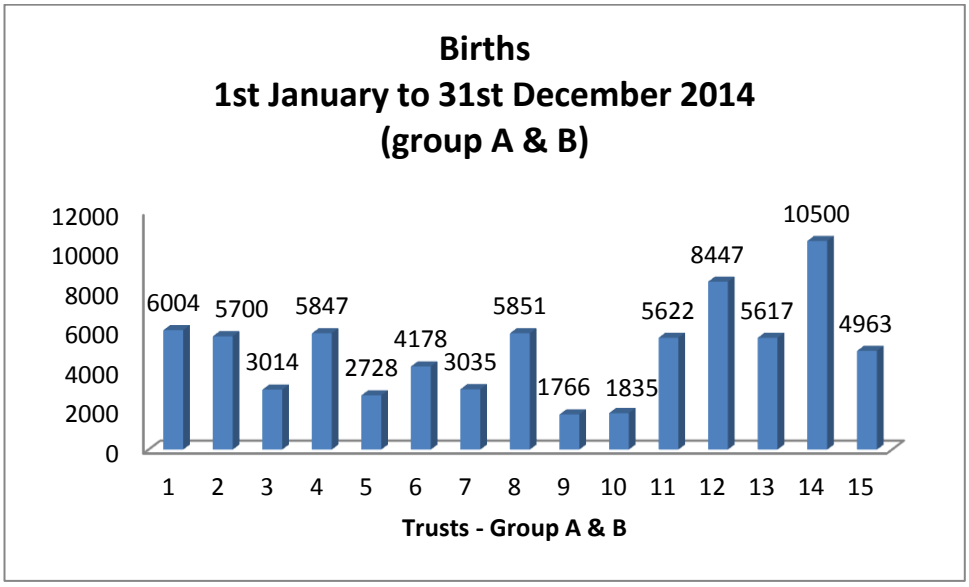
As seen in Figure PO2 there were a total of 20 responses regarding designated level of maternity services as there were varying types of service provision and service delivery sites working at different levels within one Trust . A total of 65% of Trusts (n=13) were District General hospitals of which 5% (n=1) was a geographically isolated Midwifery- led unit and 30% (n=6) were Tertiary referral units (located in Brighton, Cambridge, Hull, Norwich, Liverpool and Leicester).

Figure PO2: Level of Maternity Service



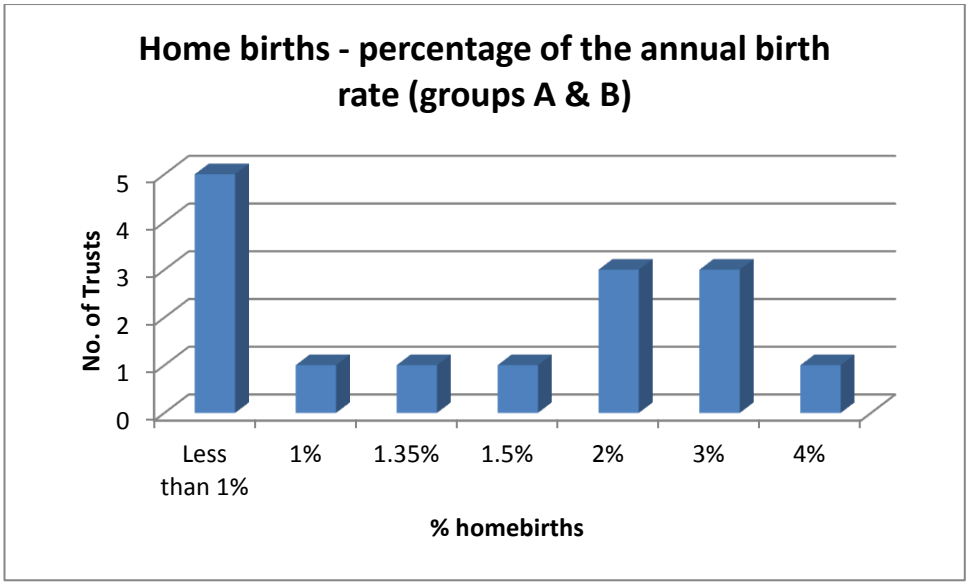
In the retrospective data period (2014) there were a total of 75,107 births for both groups in the Pilot. There were 30, 506 births in Group A (average 4,360) and 44,601 in Group B (average 4,460) The average birth rate overall was 5,007 for both pilot groups.

Figure PO3: Births Groups A and B



In line with the aims of the pilot it was important to assess the impact of undertaking newborn PO screening in different midwifery service delivery environments. In particular, the Pilot will assess the impact of undertaking newborn PO screening in the home environment and the associated requirement for pulse oximeter equipment and concordance with the screening pathway. Although taken in isolation, the numbers of homebirths were relatively low - see Figure PO4.

Figure PO4: Homebirths (%)



It was envisaged that the provision of PO screening in the home environment would also provide data on the associated workload and transport arrangements for those babies who screen positive in the community and the impact of the clinical management pathway.

A characteristics profile of the participating Trusts was developed from the questionnaire responses that provided information in relation to the differences and similarities between the Trusts selected. Table 8 outlines the pilot trusts characteristics:

Table 8: Trust characteristics criteria

Trust characteristics criteria	Number	Additional comments
Level of maternity and neonatal services	6 tertiary referral units 13 district general units 1 birthing centre	2 of the tertiary units were in group A and already undertaking PO screening pre pilot.
NIPE SMART implementation	9 Trusts using NIPE SMART pre pilot. 2 Trusts implemented early prior to Phase1 of the pilot 2 Trusts implemented prior to commencement of Phase 2 with 1 Trust implementing one week post Phase 2 commencement. 1 Trust did not use NIPE SMART	All Trusts with one exception used NIPE SMART for the collation of PO screening outcome data.
Number of homebirths	8 Trusts had a home birth rate of 1.5% or lower . 7 Trusts had a home birth rate >2%	The home birth rate was relatively low across all participating Trusts ranging from <1% - 4%

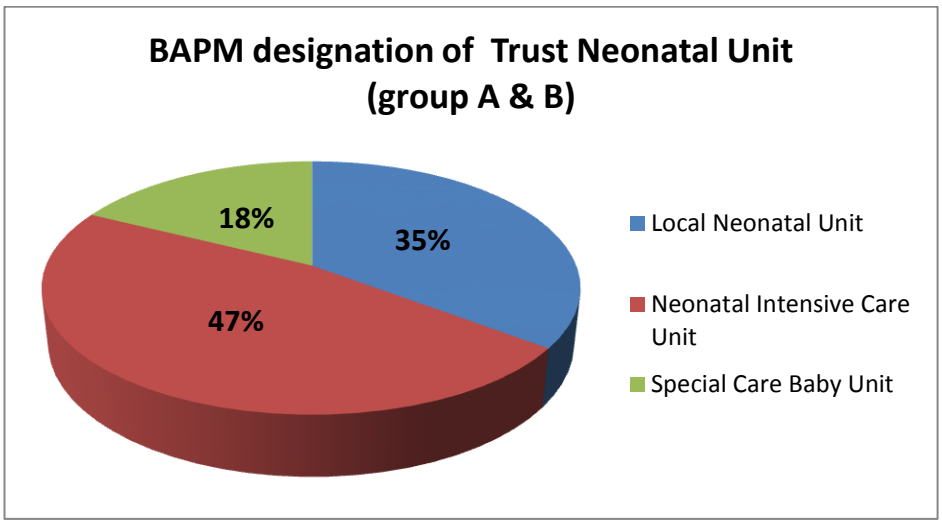
The PO variances are outlined in Table 9.

The birth rate, level of maternity service, homebirth rate distribution across all the participating Trusts provided a good representation in terms of an expected population cohort for PO screening from the retrospective birth rate data and level of maternity service.

Neonatal services provision

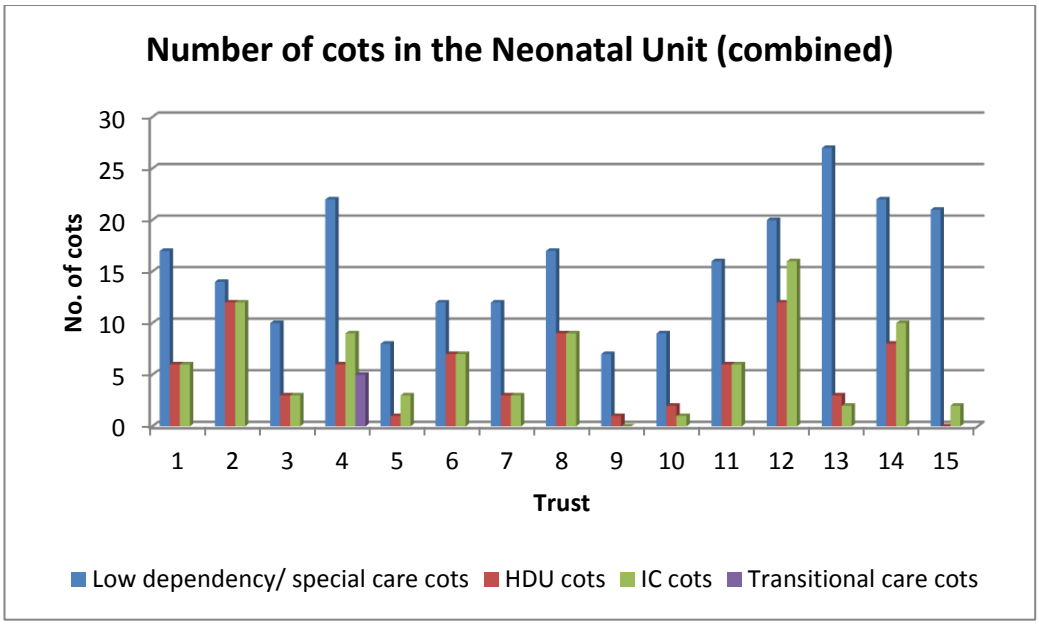
There was a good range of neonatal unit facilities in both groups of the pilot cohort. The designations used were based on the British Association of Perinatal Medicine (BAPM) definitions and included 8 neonatal intensive care units (47%) 6 local neonatal units (35%), and 3 special care baby units (18%) See Figure PO5 below

Figure PO5: Participant Trust Neonatal Units



Within both groups there were also a good mix of number of neonatal cots including transitional care cots. The total number of cots was 402 and includes low dependency/special care, high dependency (HDU), intensive care (IC) and transitional care. Number of cots in both groups can be seen in Figure PO6. The number of intensive care cots is reflected in the number of tertiary level (NICU) and Local Neonatal Unit designated units.

Figure PO6: Profile - Number of Cots Group A and B combined



Only one Trust declared transitional cots as a separate service with designated cot numbers. However, a transitional care service was provided in other Trusts in both groups. The numbers of designated cots were not provided as this information was not part of the suite of pilot questions.

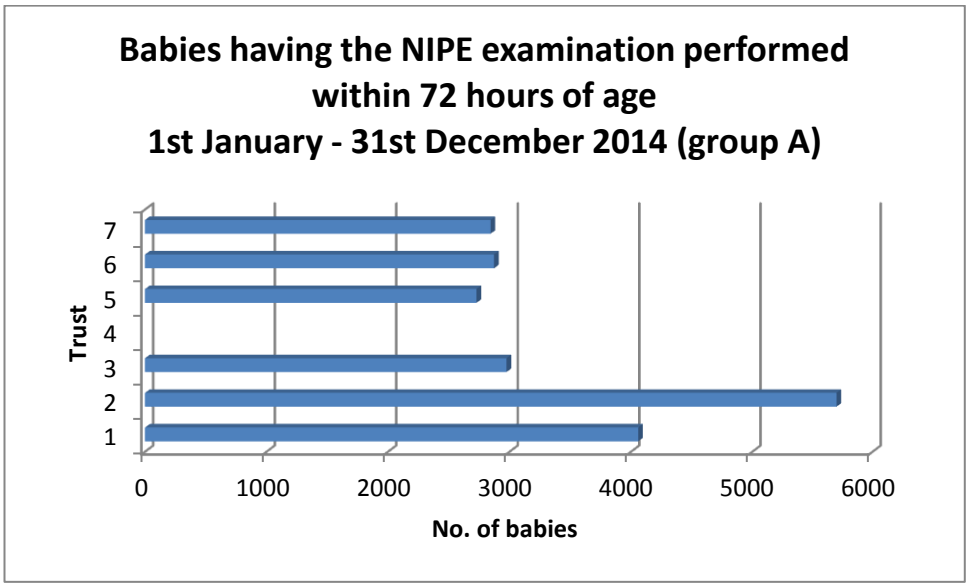
Local newborn physical examination service provision

In line with NIPE Service Specification, programme standards and key performance indicator NP1, all newborn babies born should be offered NIPE screening. Using the agreed threshold minimum, 95% of these examinations should be undertaken within 72 hours of birth.

In line with the diverse birth rate within the participating Trusts, the number of NIPE examinations undertaken daily ranged from 1 to 40, with the majority of Trusts performing between 14 and 20 NIPE examinations per day.

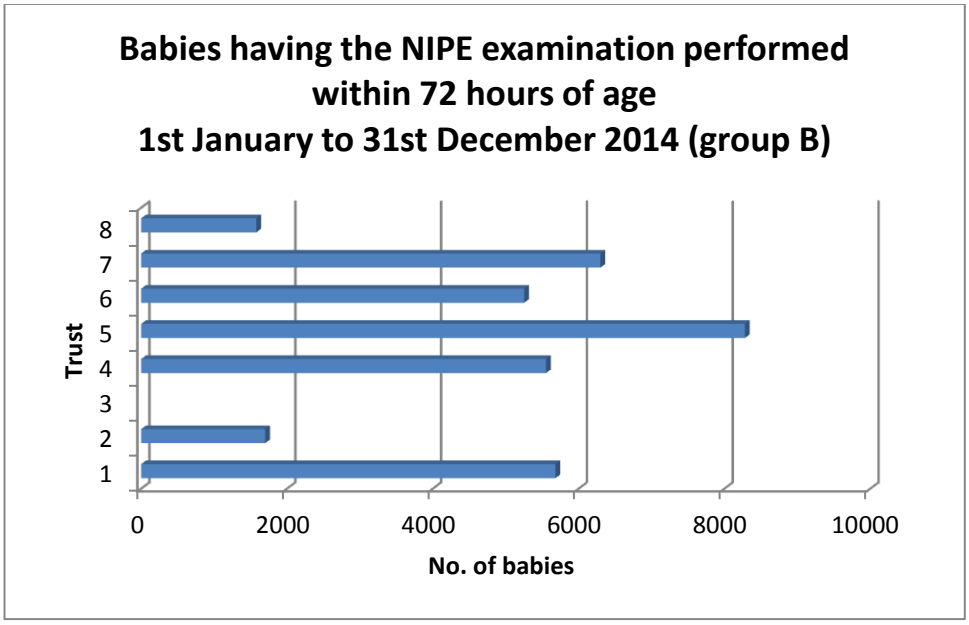
86% of babies in Group A and 77% in Group B, were examined within 72 hours. It should be noted that some data was missing as some Trusts did not have robust data collection methods in 2014 to assess coverage within 72 hours (6 submissions for group A and 7 in Group B as indicated in Figures PO7 and PO8).

Figure PO7: Group A - NIPE Examinations within 72 hours



The reason for the lack of robust data at local level for some Trusts was due to the late implementation of the NIPE SMART system which could have provided the retrospective cohort coverage data for the previous full year.

Figure PO8: Group B - NIPE Examinations within 72 hours



Note: one Trust provided no data and one only provided data for one of their two maternity services.

Early discharge from the maternity unit was offered in 76% (n=13) of pilot Trusts with 53% (n =9) routinely performing the newborn examination before early discharge. This practice is concurrent with the NIPE Programme recommendation that the newborn examination should be performed prior to an early discharge from hospital irrespective of the age in hours of the newborn. The Trusts with multiple sites provided individual site answers to this section. A total of six out of seven Trusts in Group A performed PO screening prior to early discharge. One Trust in Group A did not perform the newborn examination prior to early discharge. If discharge took place before the newborn examination was performed then 47% (n=8) of Trusts advised the return of babies to the postnatal ward environment for the examination. Other locations included home, return to the labour ward, return to designated NIPE clinic or attendance at GP surgery. One Trust indicated '*it may not get done*'. A total of 76% (n=13) Trusts conducted the newborn examination in the home environment as required.

The significance of the newborn physical examination provision across all pilot Trusts lies in the first instance with the Group A Trusts in relation to when PO screening is performed. Two Group A Trusts perform the screening at the same time as the NIPE examination. For those Trusts, alignment to the newborn PO screening pathway would mean a change to their current service model for PO screening.

Local newborn PO screening service provision

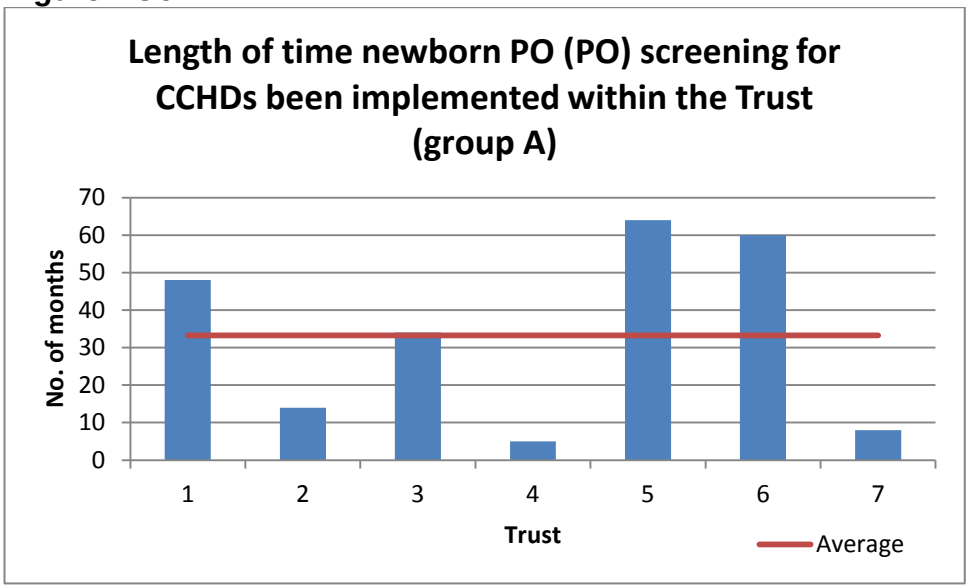
Mapped pilot objective:

- identification of existing PO screening pathways already in use within the defined participating Trusts

The collation of data from the Phase 1 questionnaire in relation to the PO screening practices demonstrated clinical variances in screening practices. The following data findings relate to the mapped pilot objective identifying the existing PO screening pathways already in use within the Group A pilot Trusts.

Trusts in Group A already had an existing newborn PO screening programme in place but were utilising different screening pathways. Three Trusts had been undertaking the screen for four or five years and one for around five months (see Figure PO9). A total of five (71%) of Trusts reported that their regional neonatal network recommended PO screening to detect CCHDs and four reported the regional neonatal network had guidelines available.

Figure PO9:



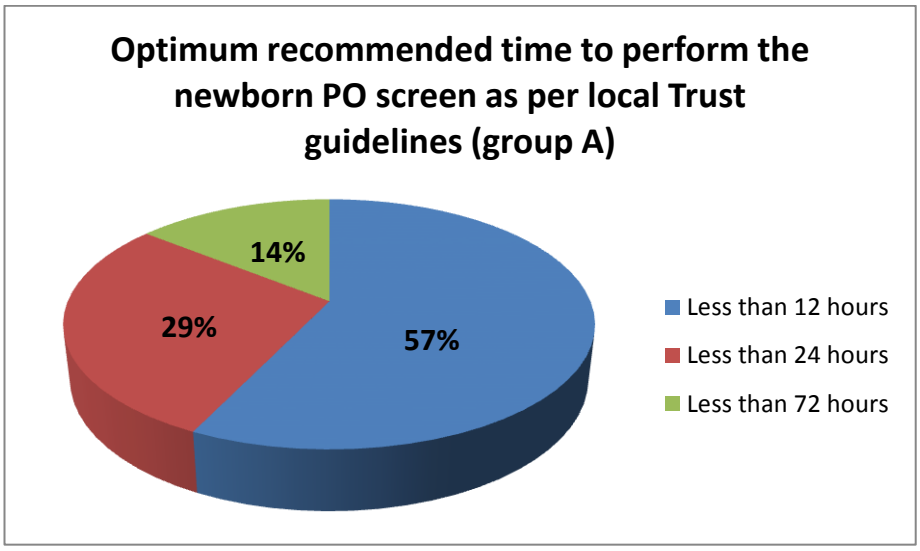
Four Trusts used pre- and post-ductal measurements and three used post-ductal only. Although 6/7 Trusts reported that clinical audit was conducted to monitor newborn PO activity, only three were able to supply data on the numbers of PO screens undertaken in 2014. These ranged from 2700–4000 screens per annum.

Trusts were asked about timing of screening. Four reported that usual practice was to screen before 12 hours of age, two reported before 24 hours of age and one less than 72 hours but there was further variance within each timescales category with each Trust having a slightly different target timescale (see Figure PO10) For the majority, the screen was undertaken before or at the time of the newborn physical examination. The majority (86%) did not

routinely offer PO screening in the home environment and only one Trust offered this service. The average length of time for Trusts having implemented newborn PO screening was 32 months. Two had been conducting PO screening for five years with one Trust having been a participant in the 'Pulse Ox' Study (Ewer et. al. 2012[1]) and had continued following its completion in 2012.

[1] Ewer AK, Furmston AT, Middleton LJ, Deeks JJ, Daniels JP, Pattison HM, Powell R, Roberts TE, Barton P, Auguste P, Bhoyar A, Thangaratinam S, Tonks AM, Satodia P, Deshpande S, Kumararatne B, Sivakumar S, Mupanemunda R, Khan KS. PO as a screening test for congenital heart defects in newborn infants: a test accuracy study with evaluation of acceptability and cost-effectiveness. Health Technology Assessment. 2012; **16** (2), 1366-5278. Health Technology Assessment HTA Programme.

Figure PO10:

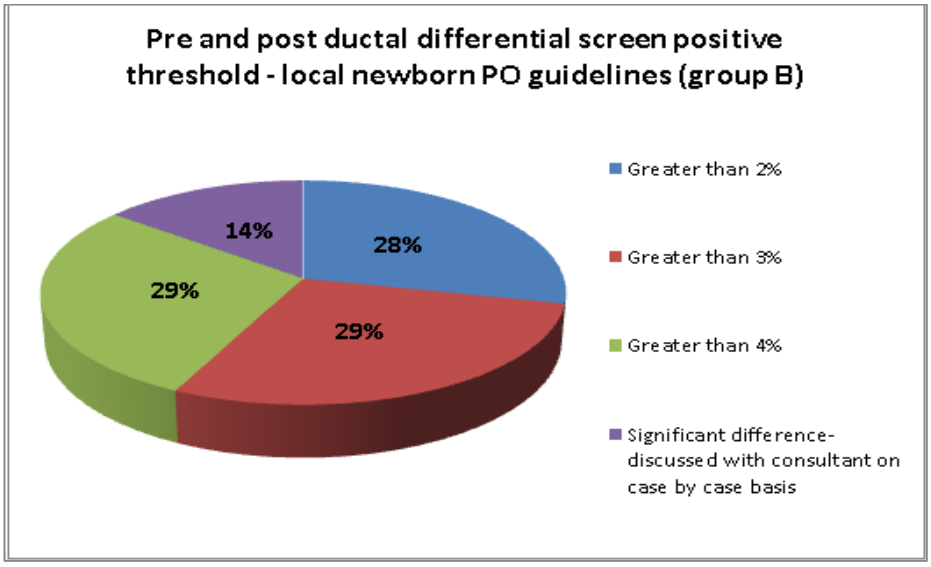


Thresholds and screening pathways

The agreed newborn PO pilot screening pathway sets the screen negative threshold as results which are greater than or equal to 95% and a difference in the pre and post measurements of less than 3%. Of the Group A Trusts, four used 95% as the screen negative threshold with three using greater than or equal to 96%. A total of 89% of the Group B Trusts used greater than or equal to 95% in those babies who had 'targeted' PO performed. Group B prior to Phase 2 of the Pilot were not conducting PO as screening but only as a diagnostic tool in 'targeted' cases i.e. when a baby was symptomatic and unwell.

Four Trusts in Group A cited a difference greater than 2% as the screen positive result threshold which required no change to their existing pathways to meet the Pilot Screening Pathway requirements and three Trusts used greater than 3% There was a greater variance in Group B with some Trusts using 4% as cut off and one using a parameter of 'significant difference'.

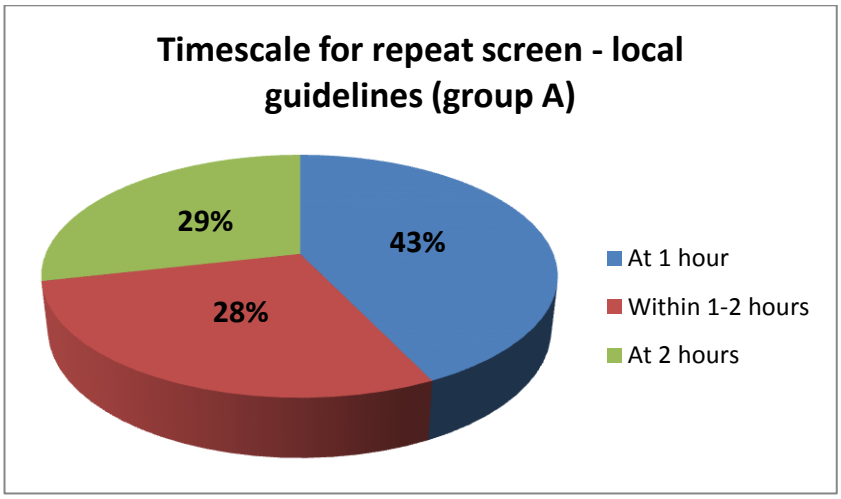
Figure PO11:



Repeat PO screening

Following an initial positive screen result that fell within the 'repeat screen' arm in local guidelines, all Trusts routinely undertook the repeat screen at or within 2 hours (see Figure PO12)

Figure PO12:



Equipment usage

The pilot Trusts were asked what pulse oximeter devices were used for screening. The most frequently used devices were supplied by Masimo. A total of 66% (n=10) Trusts used Masimo devices followed by Nellcor devices in 20% (n=3) of Trusts. One Trust used Datascope and one Trust used Nellcor via the GE Dash monitor. This particular question demonstrates that most Trusts favour one particular device manufacturer. It should be noted that although interesting to note, this information was not taken into account as part of the rigorous PHE equipment tender process.

Trust variances in local PO practices

Table 9, provides a collated summary of PO screening practices within the pilot Trusts. The table includes questions relating to PO practice and the responses. The summary table of PO practices illustrates the variances between the Trusts with respect to the screening thresholds used, sites for PO measurements and the timing of the first screen. This also reflects the variances in practices within the global evidence base.

In summary, from the Phase 1 questionnaire for pilot Trust practices in Group A Trusts:

- 85% (n=6) performed PO screening prior to early discharge
- Pre- and post-ductal site measurements were the most prevalent method across both Group A and B.
- Group B Trusts did perform PO but only in a ‘targeted’ mode whereby PO was performed as a diagnostic tool for babies that were unwell or had risk factors.
- the timing of when the PO screen was performed was not consistent across the Group A Trusts and no trend could be established.
    - four Trusts in Group A did state performing the PO screen at the same time as the newborn examination indicating that early screening i.e. 4-8 hours of age was not the most prevalent service model.
    - the remaining three Trusts in Group A stated performing the screen before the newborn examination indicating early screening.

- 73% of Trusts in both groups indicated a threshold measurement of 95% and above as a normal result with 26% of Trusts citing 96% as a normal result.

- the ‘differential’ between the pre- and post-ductal measurement was predominantly greater than 2%. The timing of the repeat screen varied between 1 hour after the first screen and 1-2 hours.

Table 9: Question	**Trust Group**	**Response criteria/'other' responses**	**Collated responses**	**Trust names**
1.Is POx performed before discharge:	A	Yes	6/7	6/7 =Bradford, Cambridge, Norfolk and Norwich, Grimsby, WOLVERHAMPTON, WARRINGTON.
		No	1/7	1/7 =Chester
	B	No	8/8	
2. Site/s used for POx measurements?	A	Pre and post ductal Post ductal only	4/7 3/7	4/7 = Chester, Grimsby, Wolverhampton, Warrington 3/7 = Bradford, Cambridge, Norfolk and Norwich
	B ('targeted POx)	Pre and post ductal Post ductal only	6/8 2/8	6/8 = Macclesfield, Hereford, Hull, United Lincs, Leicester, York 2/8 = Brighton, Liverpool
3. Optimum recommended time to perform POx as per Trust guidelines?	A only	0-5 hrs 6-8 hrs 4-12 hrs 6-12 6-24 hrs At NIPE exam <24 hrs With NIPE exam <72 hrs	1/7 1/7 1/7 1/7 1/7 1/7 1/7	1/7 = Bradford 1/7 =Wolverhampton 1/7 =Cambridge 1/7 =Norfolk and Norwich 1/7 =Grimsby 1/7 =Warrington 1/7 = Chester
4. When is POx screen performed?	A only	Before NIPE exam After NIPE exam With NIPE exam With/before NIPE exam With/before/after NIPE exam	3/7 0 2/7 1/7 1/7	3/7 = Bradford, Norfolk and Norwich, Wolverhampton 2/7 = Chester, Grimsby 1/7 = Warrington 1/7 = Cambridge
5. Where is POx screen performed?		Postnatal ward Delivery suite Home NIPE Clinic Neonatal Unit	All Trusts performed POx in the varied environments. 1/15 in the home.	
6. Is POX screening performed in the home?	A only	Yes No	1/7 6/7	1/7 = Wolverhampton 6/7 = Bradford, Cambridge, Chester, Norfolk and Norwich, Grimsby, Warrington
7. Normal POx threshold according to local guidelines?	A	95%	11/15	11/15 = Bradford, Cambridge, Norfolk and Norwich, Wolverhampton, Brighton, Macclesfield, Hereford, Hull, Liverpool, United Lincs, Leicester,
	B	96%	4/15 (Multiple site Trust didn't respond)	3/15 = Chester, Grimsby, Warrington, Scarborough
8. Differential	A	>2%	6/15	6/15 = Cambridge, Chester, Norfolk and Norwich,

threshold for screen positive result	B	 >3% >4%	 5/15 2/15 Other -1 – 'significant difference discuss with consultant on case by case basis' Group B Other 1 – 'no local guideline but <95% would be abnormal' (Group B) 1 multi-site Trust 'n/a'	Warrington, United Lincs, Scarborough 5/15 = Bradford, Grimsby, Wolverhampton, Hereford, United Lincs - Pilgrim, 2/15 = Macclesfield, Leicester 1 = Hull 1 =York
9. Time of repeat screen?	A only	1 hr 1-2 hrs 2 hrs	3/6 2/6 2/6	3/6 = Bradford, Norfolk and Norwich 2/6 = Cambridge, Warrington 2/6 = Chester, Grimsby
10. If positive repeat screen when the baby is reviewed?	A B	Immediately Within 15 minutes Within 30 mins of notification 1-2 hrs Other -As soon as possible depending on condition of baby Other - Assessed by HCP after 1st positive screen Other – 'HCP will order test and be present when performed' All categories selected Misread question	1/15 4/15 4/15 1/15 1/15 1/15 1/15 1/15 1/15	1/7 = Grimsby 4/15 = Macclesfield, Hereford, Hull, United Lincs – Pilgrim, 4/15 = Norfolk and Norwich, Wolverhampton, Warrington, United Lincs 1/15 = Chester Cambridge Bradford, Liverpool

Home environment and midwifery led unit (MLU) service provision

In relation to transport arrangements from the midwifery led units (MLUs). Only two Trusts responded to the transport arrangements question as there are two MLUs that are geographically separate from the main consultant led maternity unit in the Pilot. One Trust responded with the use of a paramedic ambulance for all transport arrangements of a baby requiring transfer from the MLU to the main unit. One Trust misread the question. If a baby required admission to the main unit 60% (n=9) of pilot Trusts admitted the baby to the neonatal unit with 26% (n=4) admitting to the paediatric ward. One Trust (6%) admitted the baby to the labour ward in the first instance and then to the neonatal unit.

The transport arrangement for the transfer of a baby (and mother) is of interest to the Pilot in terms of the potential impact on local ambulance services. In addition, subsequent impact on neonatal network transport facilities will be examined as part of the Pilot for those babies that require transfer from the community or MLU to the main consultant-led facility following a positive first PO screen. It was anticipated that those babies that require a repeat screen may be transferred into the main unit or hospital from home for the repeat.

Local paediatric cardiac referral processes

It was essential to establish the cardiac referral processes within each Trust to understand what the potential increase in referrals (as a result of the Pilot) may have upon existing local referral pathways. Both groups provided answers for this section. The referral process detail was mapped in the Phase 1 questionnaire from the point of the screen positive result. If the repeat screen was negative, a total of 10 (66%) Trusts would advocate the resumption of the normal care pathway for this cohort of babies with 20% (n=3) instigating a delayed discharge and further observation of the baby. One Trust commented that if the cardiovascular system (CVS) examination was abnormal (i.e. presence of a cardiac murmur) then discharge would be delayed for 24 hours. Another commented that if the CVS examination was normal and PO performed for risk factors/ family history then discharge would occur if both normal.

The length of delayed discharge was inconsistent across Group A. The most prevalent delay was 19-24 hours in 44% (n=4) of the Trusts who responded to the question. A total of 6 Trusts had a ‘n/a’ response to this question. Further responses included one Trust with 4-6 hours delay, 1 with 13-18 hours delay, 2 responses stated it was dependent upon the baby’s clinical condition.

An additional clinical question enquired about circumstances where a cardiac murmur was present but the PO screen was negative and baby asymptomatic. A total of 53% (n=8) Trust reported that the baby would be further assessed by a senior paediatrician with 46% (n=7) delaying discharge by 24 hours and repeating the CVS examination prior to discharge. One Trust would arrange an inpatient echocardiogram at this stage and further assessment by a

senior paediatrician. One Trust would arrange an electrocardiograph (ECG) and further assessment by a senior paediatrician.
In relation to specialist diagnostic provision, a total of 16 (94%) had a local echocardiography service where an echocardiogram would be performed in-house. Some responses from Pilot Trusts with multiple sites reflected differences in cross-site services (total 17 responses). Only one Trust did not perform echocardiograms on-site. A total of 11 (65%) of Trusts (17 responses) would consult with a paediatric cardiologist using remote communication. A local cardiac clinic service was provided by 13 (76%) of Trusts with 15 (=88%) having a joint cardiac clinic facility with a paediatrician with expertise in cardiology (PEC). If admission to hospital was necessary after discharge from the maternity unit 15 (94%) of Pilot Trusts would admit the baby to the paediatric ward. One Trust would admit to the neonatal unit.

A total of three (42%) of Trusts in Group A reported that clinical audit was not conducted to monitor the cardiac referral process within the Trust with 86% reporting that clinical audit was used to monitor newborn PO activity. Interestingly 71% of Trusts in Group A reported that the regional Neonatal Network recommended PO screening but only 43% of networks had regional guidelines in place as indicated in Figures PO13 and PO14. Conversely, in Group B only 30% of networks recommended PO screening with only 10% of networks having a regional guideline in place.

Figure PO13:

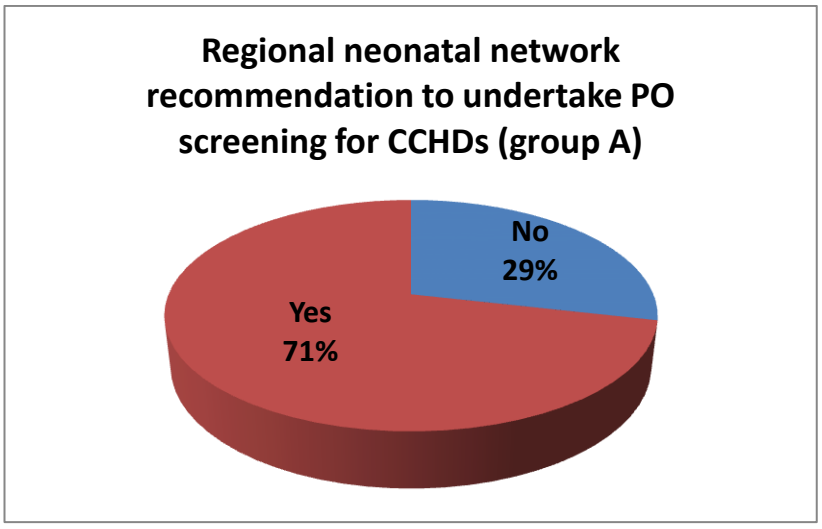
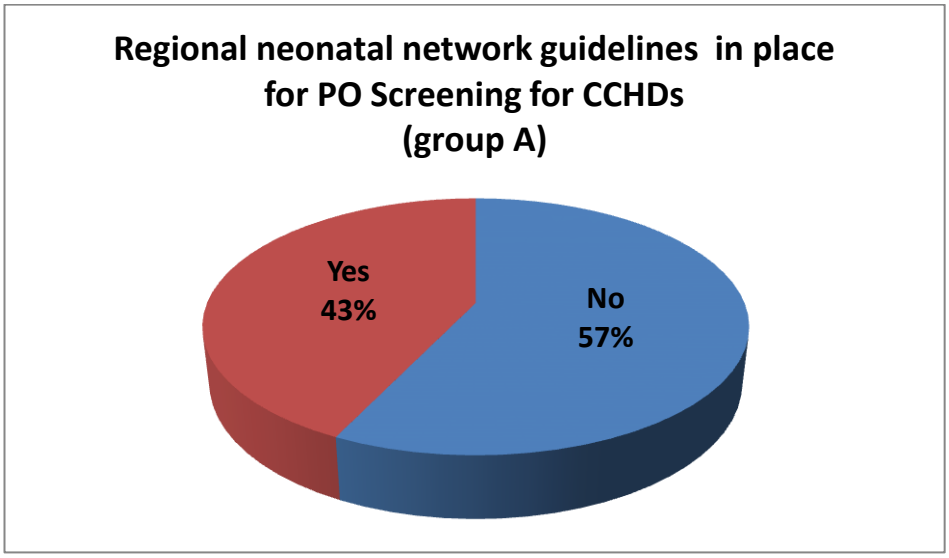
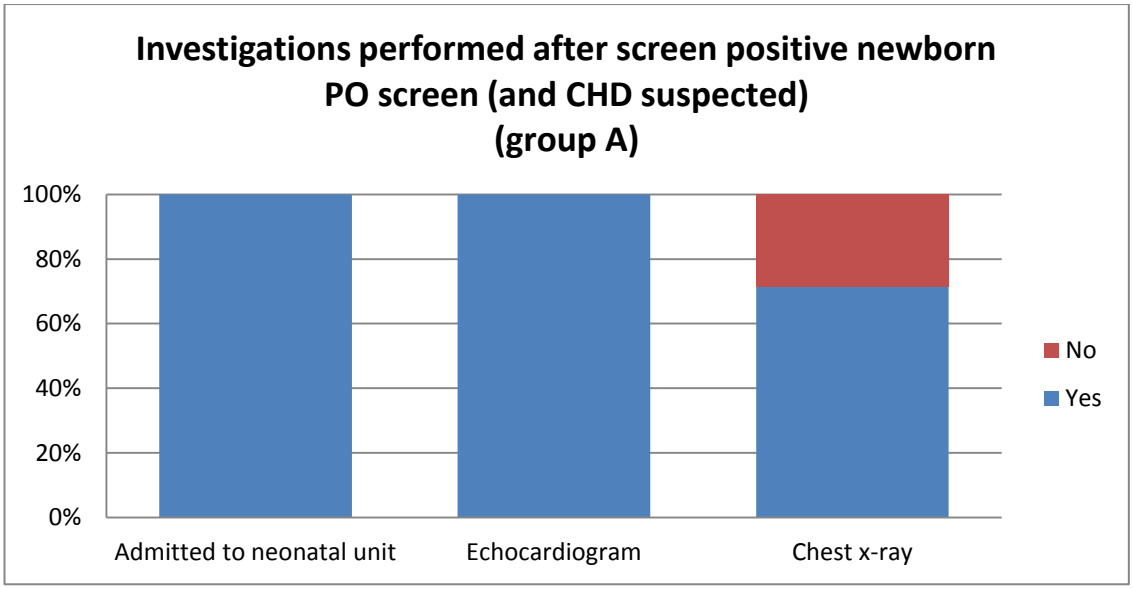


Figure PO14:



The PO screen positive management process was assessed. In cases where a CHD is suspected, Trusts were asked what investigations would usually be undertaken. In all seven Trusts in Group A, 100% of babies would be admitted to the neonatal unit and an echocardiogram undertaken. A total five out of seven would have a chest x-ray and a number of other tests were reported to be performed (see Figure 15). It was necessary to evaluate this process in Phase 1 of the pilot as the data will be used as a comparative with the Phase 2 data from all the reported screen positive cases. This will provide crucial information about the impact of PO as a routine screening test upon neonatal and paediatric clinical services particularly for those Trusts in Group B who would be performing PO as a screening programme as part of the pilot.

Figure PO15:



Education and training

All Trusts in both groups responded (including the multi-site Trusts n=17 responses) to question regarding the provision of training for PO screening. Multi-disciplinary representation was demonstrated across all the pilot Trusts in relation to training provision that included consultant neonatologists and paediatricians, middle grade and staff grade paediatricians, ANNPs, neonatal nurses, midwife and practice development nurses. A total of 76% (n =13) assessed competency for performing PO with 4 Trusts not assessing competence. Of the 17 responses to the question on the use of a competency checklist 53% (n=9) of Trusts had a local competency checklist, 2 Trusts used the device manufacturer's checklist, 2 Trusts had no documentation, three provided a 'n/a' response and one Trust commented that the 'mini CEX system' was used by trainees but referred to the newborn examination not PO.

Phase 1 Retrospective data

Each participating Trust required to provide aggregated data collected retrospectively for the six months prior to the start of the pilot. No patient identifiers were requested or required. A total of fourteen Trusts submitted data and one did not for this dataset. The dataset comprised a summary of patient numbers and service workload in order to provide an overview of service delivery. The requested data was not complete for this dataset and the data could not be analysed.

Trusts were provided with suggestions of where the data for this dataset could be sourced:

- BadgerNet system
- NIPE SMART system
- K2
- Meditech
- Other maternity service IT system

The data varied with respect to the detail supplied as trusts found it difficult to access data at these sources therefore many data fields were poorly completed. In particular, Trusts experienced difficulty in obtaining both local cardiac referral and outcome data as they often had to request this from the regional cardiac centres. Each cardiac centre was contacted (letter template attached as Appendix 7) requesting the release of these data for the purposes of the pilot. As most of the local maternity and neonatal unit data requested for the pilot were not routinely used by Trusts for audit purposes, there was considerable difficultly in interrogating local clinical investigations records. Local data entries to the BadgerNet system were inconsistent and not always complete resulting in limited data extraction from this system and other hospital IT systems.

Two Trusts accessed 'Coding' in an attempt to collate admission data. This highlighted the issue for participating Trusts that there were no processes in place to routinely track outcomes of newborn referrals for investigation. In addition communication pathways between neonatal and paediatric services were suboptimal and maternity or neonatal unit staff were not informed about post natal cardiac diagnoses.

Cardiac anomaly outcome data was submitted by the 14 Trusts with some of the data being obtained from the regional cardiac centres (Appendix 13).

This dataset within Phase 1 of the pilot has demonstrated that data collation to provide accurate and reliable data on outcomes after screening or cardiac investigation, or to demonstrate service work load, is not easily achieved through retrospective routinely collected data systems due to incomplete local recording and poor communication between information systems.

To understand the diagnostic pathway and outcomes more fully, robust collation of service workload data would be required through an on going prospective data collection model or improved linkage of existing routine systems with an additional emphasis on improved completion of data entries. A reliable way to collect such data in future would include assignment of a locally designated person with responsibility for data collection using an agreed dataset.

Phase 2 Pre-Implementation Data Findings

A baseline prospective dataset was collected within each Trust for one month (June 2015) prior to the introduction or alignment of the PHE newborn PO screening pathway. The aim was to explore some aspects of existing practice prior to the commencement of the pilot. Data was collected for each screen positive case in Group A and, for Group B, information was collected about all babies admitted to the neonatal unit at 34 weeks gestation and above with respiratory symptoms and/or suspected CHD. These data provide a limited snapshot of the investigations and management of suspected cases of CHD during the short collection period.

Only two Trusts out of seven in Group A submitted screen positive data with a total of six screen positive cases. One Trust submitted two screen positive reports with the other submitting four cases. The remaining five Trusts in Group A had no screen positive cases reported in the month of June.

A total of five babies were admitted to the neonatal unit with three babies requiring intensive care, one requiring high dependency care and one requiring low dependency care. Three of

the five cases had an echocardiogram performed. Of the three cases one baby had a PFO with ASD and small PDA. Two cases had structurally normal hearts with transitional circulation. Table 10 summarises the investigations performed on screen positive cases and Table 11 provides the diagnostic outcomes:

Table 10: Group A pre-implementation screen positive case summary

Clinical management	**n**
Chest x-ray	6
Blood gases	6
Blood cultures	6
CRP	6
Urea and electrolytes (Us and Es)	6
Full blood count	6
Chromosomal studies	3
Antibiotic therapy given	6

Five of the screen positive cases in Group A were admitted to the neonatal unit and had a wide range of investigations performed, including chest x-ray (CXR), blood gases, blood cultures and antibiotic therapy, although only three babies had chromosomal studies. One baby was not admitted to the neonatal unit but had similar investigations performed and antibiotics administered.

Table 11: Group A pre-implementation screen positive non cardiac diagnoses

Non cardiac diagnosis	n
Congenital pneumonia	3
Culture negative sepsis	4
Chromosomal abnormality with hypotonia	1

N.B one baby had a diagnosis of congenital pneumonia *and* culture negative sepsis

There were no re-admissions of these babies with symptoms of hypoxaemia or suspected CHD following discharge from the maternity services.

In Group B, there were a total of 38 babies reported admissions to the neonatal unit in June 2015. One Group B Trusts did not submit details for the case identified and this case was omitted from the overall data. There was one baby admitted to the paediatric ward with a cyanotic chocking episode following a planned home birth.

Table 12 summarizes the investigations, clinical management and diagnostic outcomes of the Group B neonatal unit admissions:

Table 12: Group B pre implementation period clinical investigations and management (n 37)

Clinical management	n	%
Chest x-ray	25	66%
Blood gases	27	71%
Blood cultures	31	81%
CRP	30	79%
Urea and electrolytes	24	63%
Full blood count	30	79%
Antibiotic therapy given	30	79%
Echocardiogram	2	5%
Prostin infusion	2	5%

In Group B, there were 66% (n 25) babies admitted to the neonatal unit who had a CXR performed, 81% (n 31) had blood cultures taken and 79% (n 30) received antibiotic therapy.
There were three babies who were admitted to the neonatal unit and subsequently found to have a diagnosis of CCHD/CHD. All of these babies were admitted from the maternity unit. There were no cases of readmission from home with symptoms of hypoxaemia or suspected CHD following discharge from the maternity services. Two echocardiograms were performed locally and another was performed at the regional cardiac centre. There were three cardiac diagnoses in this group, two CCHDs and one CHD. The two CCHD cases required Prostin infusions. Table 13 provides the list of cardiac diagnoses within this group.

Table 13: Group B pre implementation cardiac diagnoses

Cardiac diagnoses	n
Membranous pulmonary atresia, moderate-severe TR,PDA	1
Small ASD and PDA, Trisomy 21	1
Transposition of great arteries	1

Table 14: Group B pre implementation non cardiac diagnoses

Non cardiac diagnoses	n
Congenital pneumonia	2
Culture positive sepsis	1
Culture negative sepsis	15
TTN requiring oxygen	4
Transition circulation	8
Chocking episode	1

Non cardiac diagnoses 'other'	n
Cleft palate, feeding difficulties and hypoglycaemia	2
Hyperbilirubinaemia and poor feeding	1
Chocking episode self limiting	1
TTN	1
Treated as necrotising enterocolitis	1
Apnoea ? seizures	1
Suspected sepsis	1
Transient hypoglycaemia	1
Respiratory distress of newborn	1
TTN treated with cpap, no oxygen	1

N.B. There were four cases with more than one diagnosis e.g. culture negative sepsis and necrotising enterocolitis.

The data submitted from both pilot groups for the pre implementation period provides very limited information about current practice . Screen positive babies were offered appropriate investigation and a diagnosis was made in all screen positive cases without the need for cardiological referral to a cardiac centre. Two babies in the unscreened Trusts were diagnosed with CCHD. There were no cases of readmission from home with symptoms of hypoxaemia or suspected CHD following discharge from the maternity services.

To gain a more complete understanding of the frequency and management of suspected cardiac diagnoses in order to compare practice before and after the introduction of pulse oximetry screening, it would be necessary to collect detailed information prospectively over a longer period of 6-12 months. Ideally prospective data collection would include not only details of investigation and management of suspected cases, but also baseline information in an unscreened population about the number of admissions to the neonatal unit, and referrals for cardiological investigation or echocardiography.

Section two

Phase 2 data findings: NIPE SMART PO activity coverage data

Mapped pilot objectives:

- description of the variation between those Trusts in respect to clinical workload and resources associated with implementing routine PO screening as a new screening test carried out on newborns
- audit screening outcomes in all eligible babies: all cardiac diagnoses, non-cardiac diagnoses in screen positive babies, referrals after a positive cardiovascular screen following NIPE or PO, deaths within 1 month of birth, through the collection of data and analysis

The Phase 2 data findings address the mapped pilot objectives above. Data to inform this objective was collated from the NIPE SMART IT system in 14 pilot trusts and the EPIC hospital information system (HIS) in one trust. These data were reported prospectively from the 1st July until 31st December 2015 during this Phase of the pilot.

NIPE SMART coverage data was provided weekly by Northgate from the 1st July (commencement of Phase 2 of the pilot) for the first two months of Phase 2. Each pilot Trust had been provided with their respective data set activity. The initial data reports for July and August were rudimentary in content providing only coverage. A further more detailed report and reporting items including weekly coverage breakdown, timing of the first and repeat screens, collated reasons for deviation from the screening pathway and practitioner activity was provided to the pilot Trusts in the latter part of Phase 2.

The development of the NIPE SMART PO screens not only collated screening coverage data but would also test the validity and feasibility of the Newborn PO Screening Pathway in terms of the screening thresholds and recommended timing for screening.

A total number of 33,557 babies from the 14 pilot Trusts using NIPE SMART were eligible for PO screening from the 1st July -31st December with 5.97% (n= 2132) (denominator of total cohort population n 35,689) non-eligible for screening.
Eligibility for PO screening was all asymptomatic newborns not on the neonatal unit at 34 weeks gestation and more.

The exclusion criteria for PO screening is as follows:

- presence of a suspected cardiac lesion from the fetal anomaly scans (national risk factor)
- symptomatic newborn with a history of tachypnoea, cyanosis and/or poor feeding prior to PO screening
- symptomatic newborn admitted to the neonatal unit prior to PO screening

The NIPE SMART PO first screen data field was designed with a drop down menu for non-eligible status. A more detailed analysis of this status is provided in pg. 90.

The screening coverage for the pilot from the NIPE SMART data was 90%. A total of 99.33% (n = 29,909) had a negative screen result with a 0.67% (n = 204) positive screen result rate.

The overall rate for ‘missed’ (eligible babies whose outcome is 'Missed' or 'Incomplete - Repeat Missed’) cases over the Phase 2 data collection period was 3.2% (n 973) of the total eligible cohort group. The term ‘missed’ in the context of the pilot is where an entry has been made on the baby’s record on NIPE SMART that the PO screen had not been performed due to being missed at first screen or at repeat screen.

53 parents (0.16%) declined PO screening. This total is the combined decline at the first and repeat screen (see post pilot questionnaire section for more details).

The number of babies with ‘unknown results’ decreased steadily over the data collection period. Overall 10% (n 3,397) had unknown results from the eligible population. Of this figure the cohort of ‘no results recorded’ accounted for 61% of this total. This figure was proportionate to the increasing number of screens performed over time. The ‘unknown results’ cohort includes the ‘no results recorded, awaiting repeat screen’, ‘missed’, incomplete screen results and ‘screen not done’ for other reasons.

Table 15 provides a summary of the unknown screen results from the NIPE SMART system and from the non NIPE SMART Trust

Babies with no results recorded are those babies from the eligible cohort population that had no screening result entered on NIPE SMART. The main possible reasons for this significant number are explored and discussed further in the ‘Workforce impact of PO screening’ section.

Table 16 provides a detailed data review table of the screening outcomes from the NIPE SMART for the PO pilot screening activity from 1st July to 31st December 2015.

Table 15: NIPE SMART data flowchart 1st July-31st December 2015

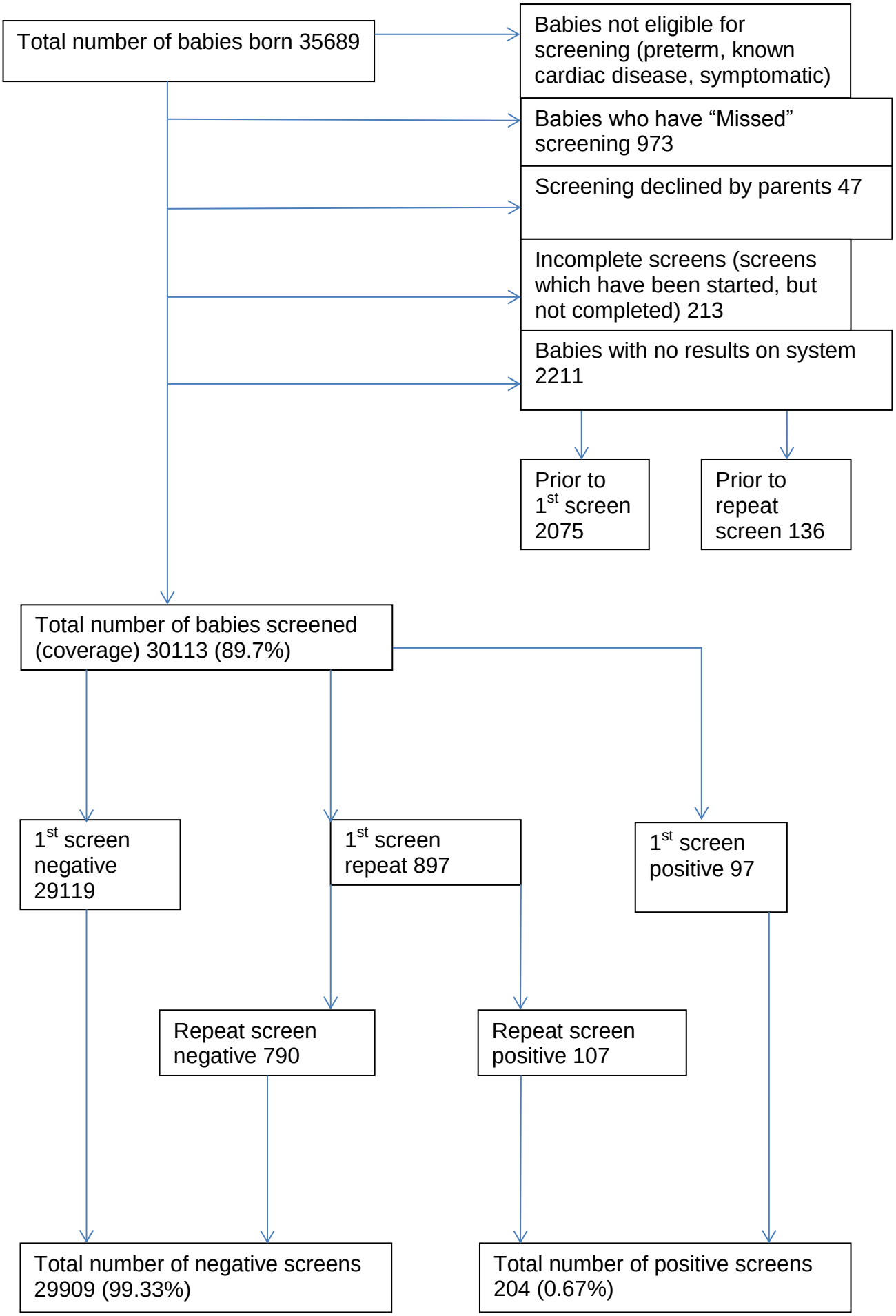


Table 16: Newborn PO Pilot NIPE SMART Data Review Table – Unknown results 1st July to 31st December 2015

	Unknown results											
NIPE SMART Newborn PO Data 1st July – 31st December 2015	**No results recorded**		**Screen not performed (Missed)**		**Incomplete screening (repeat not done)**		**Awaiting repeat screen**		**Screening not done – 'Other'**		**Total unknown results**	
	n	%of eligible babies	n	%of eligible babies	n	No. of neg +pos screens	n	No. of neg +pos screens	n	%of eligible babies	n	%of eligible babies
	2,075	6.2%	935	2.7%	38	0.12%	136	0.45%	213	0.6%	3,397	10%
Non NIPE SMART Trust Data	n/a	n/a	23	0.8%	12	0.43%	n/a	n/a	n/a	n/a	23	0.8%
Combined data	2,075	6.2%	958	2.6%	50	0.15%	136	0.45%	213	0.6%	3,420	9.4%

Timings of first and repeat screens

In order to evaluate the adherence to the newborn PO screening pathway by the pilot trusts it was essential to determine when the first and repeat PO screens were being performed by all Trusts. The screening pathway (see Appendix 1) recommends that the first PO screen is performed between 4 and 8 hours of age. The repeat screen where required was recommended two hours after the first screen. Table 17 outlines the percentage of screens performed to a stratified time interval.

From the timing data collated from the NIPE SMART system, 13.3% of first PO screens were performed between 0-3 hours, 52% at 4-7 hours, 13% at 8–11 hours, 7% at 12 -17 hours, 6% at 18-23 hours, 7% at 24-47 hours , 1% at 48-71 hours and 0.55% > 72 hours.

From this cohort it is clear that the majority (52%) of first PO screens were performed at 4-7 hours, however there were a significant number of first screens performed at 0-3 hours of age. This reflects the model of early screening adopted by two Trusts where the first screen was performed either on labour ward prior to transfer to the postnatal ward or immediate upon arrival on the postnatal ward. In addition to facilitate early discharge directly from labour ward would necessitate early screening. In the case of homebirths it is likely that early screening has taken place before the midwife left mother and baby. Three Trusts appeared to screen later than the others and it can be seen from Table xx that this reflected either the practice of screening with the NIPE exam or the screening model which utilised hearing screeners. 11/14 NIPE SMART Trusts had a median screening time of within 8 hours.

Importantly most babies (78%) were screened within 12 hours and only 8% were screened after 24 hours.

Table 18 outlines the PO timings of the Group B Trusts only

Table 19 outlines the median timing of screening by Trust

Table 17: Timing of screening - All sites. (Includes incomplete screens)

Timing of 1st screen:	
0-3 hours	4335 (13%)
4-7 hours	17039 (52%)
8-11 hours	4136 (13%)
12-17 hours	2462 (7%)
18-23 hours	2004 (6%)
24+ hours	2764 (8%)
Not documented	313 (1%)

Proportion screened 4-12 hours = 65%, before 18 hours = 85%, and before 24 hours = 91%,

Table 18: Timing of screening- Group B Trusts only. (Includes incomplete screens)

Timing of 1st screen:	
0-3 hours	4335 (13%)
4-7 hours	17039 (52%)
8-11 hours	4136 (13%)
12-17 hours	2462 (7%)
18-23 hours	2004 (6%)
24+ hours	2764 (8%)
Not documented	313 (1%)

Proportion screened 4-12 hours = 65%, before 18 hours = 85%, and before 24 hours = 91%,

Table 19: Median timing of screening by Trust

Trust	Group	Median timing
Bradford	A	0-3 hrs (75.3%)*
Chester	A	4-7 hrs (55.3%)
Norfolk and Norwich	A	4-7 hrs (61.9%)
Northern Lincs and Goole	A	24-47 hrs (23.7%)**
Royal Wolverhampton	A	4-7 hrs (92.1%)
Warrington	A	24-47 hrs (30.4%)**
Brighton Hospitals	B	4-7 hrs (76.4%)
East Cheshire	B	4-7 hrs (62.7%)
Hull and East Yorkshire	B	4-7 hrs (67.4%)
Liverpool Women's	B	4-7 hrs (63.3%)
Lincoln Hospitals	B	18-23 hrs (24.3%)***
Leicester Hospitals	B	4-7 hrs (62.2%)
Hereford	B	4-7 hrs (61.1%)
York Hospitals	B	0-3 hrs (57.6%)†

* Continued local practice of early screening. ** Continued local practice of screening with NIPE
*** Opted to screen by hearing screeners. † Opted to screen early

Reasons for deviation from the screening pathway timing

It was essential to understand each and every deviation from the recommended 4-8 hour time interval within which to perform the first PO screen. The reasons for deviations from the screening pathway by clinical staff would help inform any workload or staffing issues in relation to the implementation of either the pilot screening pathway for the Group A trusts or PO screening for Group B trusts. This information was crucial in defining clinical workload and resources associated with implementing routine PO screening as a new screening test.

The NIPE SMART system was programmed into stratified time intervals in order to detect to minor deviations (including breaches from a few minutes to hours). In all cases of deviation, the NIPE SMART system required entry of a mitigating circumstance to account for the breach. Data from a drop-down menu within the data fields for both the first screen and the repeat screen enabled collation of information regarding deviation from the screening pathway. It was necessary to identify a limited number of options to enable any analysis. The drop-down options were listed as follows:

- early discharge
- time constraints
- staffing constraints
- equipment unavailable

- mother and baby unavailable
- routine Trust practice
- other

Table 20 details the number of entries made to the NIPE SMART system for each category of deviation from the screening pathway timing for first and repeat screens combined:

Table 20: Data entry onto NIPE SMART

Deviation from screening pathway timing category	Number of entries made to the NIPE SMART system
Early Discharge	**411**
Time Constraint	**1963**
Staffing Constraints	**4008**
Equipment Unavailable	**53**
Mother and Baby unavailable	**206**
Routine Trust Practice	**6181**
Other	**2311**

Routine Trust practice is cited as the main reason for deviating from the screening pathway followed by staffing constraints. The definition of 'staffing constraints' within the context of the pilot could reflect suboptimal staffing levels within the maternity service that impacts upon the ability to undertake additional tasks. Therefore, this may not reflect lack of capacity to undertake PO but other clinical workload priorities may have arisen at the time of screening. This analogy may be replicated for other time specific ward based observations or tests.

In analysis of the data it had been noted that there may have been some miscategorisation in particular where the 'staffing constraints' option was selected on NIPE SMART where it is thought 'routine practice' should have been selected. The 'other' category feature significantly on this list. The 'other' reasons for deviating from the screening pathway are provided in the next section.

When the pilot screening pathway was developed it was agreed that the 'optimal time' for screening was 4-8 hours, however this was opinion rather than evidence-based and some flexibility was prescribed so that the caveats 'normally within 4-8 hours' and 'must be completed before discharge' were also added. The pathway also states that for early discharges screening should be performed at 4 hours and for later discharges around 8 hours. Within these contexts the fact that 78% of babies were screened within 12 hours is a considerable achievement .

In the original Pulse Ox study screening was recommended within 24 hours and definitely before discharge and within that study 25% of screens were performed within 0-6 hrs, 6-12 hrs, 12-24 hrs and >24 hrs respectively.

Table 21 outlines the stratified timings for the first PO screen.

These data indicate that the majority of first PO screens performed by the pilot Trusts were between 4 and 7 hours of age and comply with the screening pathway. One Trust in Group A and one in group B performed early screening with the predominant time to first screen being 0-3 hours. One of the main factors for deviation from the screening pathway for both Trusts was ‘routine practice’; one Trust performed early PO screening on arrival of mother and baby on the postnatal ward. The other similarly performed early screening on the delivery suite or on arrival to the postnatal ward. The Group A Trust had an established model for PO screening prior to the pilot. Their data would indicate this model did not alter to align with the pilot screening pathway.

A further two Trusts in Group A had pre-pilot models of performing PO screening with the NIPE examination. Their data also indicates non-alignment to the pathway with time to first screen as 24-47 hours. Both had confirmed at the start of the pilot that alignment to the screening pathway in terms of timing may not be possible due to staffing. Performing PO screening at the time of the NIPE examination worked well for them. To introduce another tier of staff to perform PO screening independent of the NIPE examination was not felt to be possible by these Trusts.

A total of six of the eight Trusts in Group B had a majority of first PO screens performed at 4-7 hours. One in Group B had a routine practice of the hearing screeners performing the PO screen as indicated with the timing to first screen 12-17 hours and 18-23 hours respectively on each Trust site.

In summary, three Trusts from Group A had a majority of first PO screens performed at 4-7 hours to comply with the screening pathway and Three did not comply with the screening pathway with one performing early and two performing late PO screening. Six out of the eight Trusts in Group B had the majority of first PO screens performed at 4-7 hours. One performed early screening and one later screening. In total nine out of the 14 Trust using NIPE SMART had the majority of first PO screens performed at 4-7 hours.

Table 21: Time to first screen in hours (14 Trusts) 1st July – 31st December 2015

Time to first screen in hours (14 Trusts)															
0 -3 hours		**4 -7 hours**		**8 -11 hours**		**12 -17 hours**		**18 -23 hours**		**24 -47 hours**		**48 -71 hours**		**>72 hours**	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
4034	13.3%	15690	52%	3740	12.3%	2278	7.5%	1920	6.3%	2164	7.1%	326	1%	168	0.55%

Note:

% denominator = total number of first screens (n 30,320)

Table 22: Time between first and repeat screens (within hour) (14 Trusts) 1st July – 31st December 2015

Time between first and repeat screen (within hour) (14 Trusts)									
1 hour		**2 hours**		**3 hours**		**4 hours**		**> 4 hours**	
n	%	n	%	n	%	n	%	n	%
59	6.8%	154	17%	411	46.8%	62	6.9%	211	23.5%

Note:

%denominator = total number of repeat screens (n 897)

The timing of the repeat screen was also collated by NIPE SMART. The repeat screen timings were stratified in one hour intervals from 1-4 hours and more than 4 hours as outlined in table 23. At 1 hour after the first PO screen 7% (n 59) of repeat screens were performed, 17% (n 154) at 2 hours, 47% (n 411) at 3 hours, 7% (n 62) at 4 hours and 23% (n 211) over 4 hours. If the data of repeat screens at 2 and 3 hours are combined the overall all incidence would be 63% (n 565) indicating that 2-3 hours is the most prevalent time to perform the repeat PO screen. Interestingly 23% of the repeat screens are performed after 4 hours of age. The reasons for deviation from the screening pathway are discussed in the following section.

Deviation from screening pathway for 'other' reasons

A total of 2311 entries were made on the NIPE SMART under the 'other' category for deviating from the screening pathway. The entries have been themed from the most prevalent of those entries in Table 23 as follows:

Table 23: Themes from 'other' deviation from screening pathway category

'Other' category for deviating from screening pathway timing – first PO screen	**Examples of comments entered on NIPE SMART**
Mother clinical	'Mum on HDU' 'Mum on ITU no access to notes' Mother unwell after caesarean section
Baby clinical	Cannula in situ Multiple entries for baby on the neonatal unit
Home birth	BBA Homebirths Home birth –screen done with NIPE exam
Documentation	Date and time not documented 'not documented' (multiple entries) Exact time of screen not documented Unable to find documentation 1st screen incompletely documented
Missed and timing	'missed at 3 hours' 'missed at right time 'missed at routine time – picked up at time of discharge
Unknown reason	'unknown' reason (multiple entries) 'unknown why delayed' 'Only had pre ductal saturations done at 3

	hours for unknown reason. Late had both pre and post ductal screen'
Communication	'Baby not entered onto list for check on postnatal ward' 'inadvertent omission following transfer from labour ward to postnatal ward' 'poor communication on handover from labour ward to postnatal ward' 'handed over PO done but not 'recorded on form or on NIPE so repeated'
NIPE examination	'baby discharged and back for the NIPE exam 'done as part of NIPE check 'not done prior to NIPE check'
Staffing	'staff unable to do as busy' 'late because of activity on ward'
Screening pathway	'staff not aware of protocol' 'unaware needed to do at first, baby on NNU initially as mum unwell and babies needed obs. Screened once realised'

The selected examples above illustrate some of the clinical issues experienced by the practitioners. Many of the entries reflect the model of the PO screen being performed by a practitioner before the NIPE examination and the screening result entered by a different person at the time when the NIPE examination screening result is entered.

Repeat PO screen deviation from screening pathway timing

There were 143 entries on the NIPE SMART for deviations from the screening pathway timing for the repeat screens. This is proportionate to the much lower number of repeat screens in relation to the first screen numbers. Only one Trust did not have entries for this field and two hospital sites of another Trust.
The deviation from the screening pathway menu data items mirror those of the first screen. Examples from the entries entered in the deviation from screening pathway 'other' are provided in appendix 15.

Very clear themes have emerged from the 'other' category for deviation from the pathway for the repeat screens. Multiple entries for the repeat screen being identified and performed at the time of the NIPE examination. This would reconcile with the findings from the timings of the repeat screen with 23% performed more than 4 hours after the first screen. This also implies local issues with staff not understanding the screening pathway whereby the need for a repeat screen is not identified. In addition, the need for a repeat screen would be instantly highlighted on the NIPE SMART system had the results from the first screen been entered at the time of the screen.

The delay in entering the first screen results has had an impact upon the repeat screen being identified and the timing of the repeat screen has been delayed as a consequence. However, the timing in terms of the prospective pilot period as to when these entries were made is not identifiable and therefore may have been made early in the prospective pilot period (alignment to the screening pathway for Group A and commencement of PO screening for Group B).

Some entries of the reasons for deviation from the screening pathway indicate a misinterpretation of the screening pathway in terms of the criteria for a repeat screen. Again, entry of the screening results at the time of the first screen on the NIPE SMART system would guide the practitioner on what action was required.

Documentation issues are also evident from the entries made on NIPE SMART. Handover of information and results on the PO screen at local level would appear to be an issue along with the recording of the PO screen in the newborn medical records. Three Trusts implemented a 'sticker' system whereby the PO screening results were manually recorded on the sticker and placed in the medical records for subsequent entry to NIPE SMART. This was undertaken by another staff member or by the NIPE practitioner at the time of the NIPE examination which reflects the locally developed model of data entry to NIPE SMART. The aim of this system within these Trusts was to minimise the number of babies missing the PO screen on the labour ward or before early discharge from labour ward to improve the communication between the labour ward and postnatal ward. Some other Trusts utilised such a system for documenting screening results in hard copy records for later data entry on to the NIPE SMART.

There was some evidence of miscategorisation from the drop down menu options; in particular those babies that were transferred to the neonatal unit at the time when the repeat screen was required. However, transfer is not a reason for delay in undertaking the repeat screen although some babies in this group would likely be ineligible for repeat screen.

There was a minimal number of entries for the repeat screen delay due to staffing and time constraints. This may be due to the number of repeat screens performed at the NIPE examination.

Non eligibility for 'other' reasons data fields

The NIPE SMART data fields included a drop down menu to capture the reasons as to why a baby was non eligible for PO screening. The menu data items are as follows:

- Admission to NNU
- Symptomatic prior to screen
- Non-eligible – other reason

The non-eligible ‘other reason’ data was collated by the system and the following details an example of the reasons captured:

- Admission to the transitional care unit
- Home delivery
- Admission to the paediatric ward
- Baby on methyldopa
- No NHS number available
- Early discharge
- Missed – baby feeding
- Ward busy
- PO carried out by SCBU staff as heart murmur present
- Discharged out of hours

In one Trust (with two hospital sites) the hearing screeners performed the PO screening with junior medical staff undertaking the ‘out of hours’ screening. This Trust was a district general hospital. The main reason cited for non-eligibility was discharge ‘out of hours’. Some babies did not have the PO screen due to the screen not being performed by the paediatrician. In this particular Trust the midwives did not perform PO screening. This is an important element in understanding how this Trust had utilised the hearing screeners for PO screening and that the ‘out of hours’ model may have presented some challenges.

A total of six Trusts entered non eligible ‘other reason’ on the NIPE SMART. A total of 45 babies had been entered on NIPE SMART under this category. It can be noted from the reasons provided that some should have been entered on NIPE SMART as ‘missed’ and have been incorrectly entered under non-eligible as many of the babies in the above cohort would in fact have been eligible for PO screening.

Other reasons for screen not done

It was important to understand the other reasons for the PO screen not being performed. Again the new NIPE SMART screens were designed to capture these data in a free text box for screen not done ‘other reason’. A drop down menu was provided with the following options:

- Screen not done – baby not eligible
- Screen not done – missed
- Screen not done – other reason.

A total of nine Trusts (43 babies) were entered data for this field. Table 24 is an extraction of examples of some of the 'other reasons'. The examples have been themed to be more representative of the issues:

Table 24: Other reasons for 1st PO screen not done

Service theme	Reason listed
Clinical	Cannula in situ 'Went for sepsis screen on SCBU' 'Baby on NICU' 'PO carried out by SCBU staff whilst on SCBU for short time' 'Distressed baby needing to breastfeed at mums request' 'Not done as baby is currently still in SCBU'
NIPE SMART system	'NN4B crashed and patient did not some across to eSP so screeners unaware of baby. Discharged home same day' 'Baby allocated a different surname so did not show up on the system – therefore missed' 'No NHS number put on later'
Screening pathway	'Over 4 hours old' 'Over hours old'
Training	'Training needed'
Equipment	'PO machine not working'
Service workload	'Not informed on time by midwife' 'Ward been very busy' 'Delay passed on'
Missed	'Missed by Paeds' 'Missed by screeners/paeds'

Some of the above examples should have been entered under the non-eligible' category as in some instances the baby was already on the neonatal unit at the time when the PO screen would be due; therefore would be exempt from screening. However, the data collated from having this field on the NIPE SMART has illustrated primarily the clinical and service work load issues that have impacted upon this cohort of babies that did not receive PO screening. The data captured by this field alone does highlight some of the service issues experienced and that some babies did miss screening due to existing workload and the a level of burden upon workload at that particular time compounded by apparent lack of understanding and application of the screening pathway.

It was not possible to identify from the final report received from Northgate Public Services (UK) (NPS) exactly when these incidences were logged to the NIPE SMART

system but it would indicate that some occurred early in the Phase 2 prospective period as ‘training needed’ logged as a reason and a misunderstanding of the screening pathway when ‘over 4 hours old’ logged as a reason for not performing the screen.

One of the large tertiary Trusts experienced the highest number of service workload issues with the ‘ward being busy’. The babies listed as on the neonatal unit should have been entered as non-eligible.

In respect to equipment one Trust did log that the PO device was not working. This Trust did report one device to be dysfunctional. It was returned to the manufacturer for repair and returned to the Trust in working order.

Delayed discharge due to repeat screen

As part of the evaluation of service workload of the pilot It was important to establish if there was any measurable delay in the discharge of mothers and babies as a result of PO screening. Delayed discharge is described in this context as a change to the anticipated or planned discharge time of the baby. This did not include maternal issues or maternity service capacity reasons. Any baby that was found to be symptomatic at the time of the first screen would not be for be considered fit for discharge. Delayed discharge as a result of PO screening would only relate to babies awaiting a repeat screen or are found to be symptomatic at the time of the repeat screen. The question ‘Discharge delayed as a result of the repeat PO screen?’ was included as a data field on the NIPE SMART system to capture data regarding this workload question.

A total of 7 Trusts logged entries to this field with a total of only 12 entries (1.3%) out of a total of 897 repeat screens performed. Reasons included:

- ‘baby would have had a 6 hour discharge’
- ‘repeat screen negative, patient wanted to leave at 5:00pm’

Babies with a screen positive result also experienced delay in discharge as discussed in the positive screen data findings section (pg. 108)

Overall the evidence presented suggests a minor delay in discharge as a result of PO screening mainly in the screen positive cases.

Workforce impact from the implementation of PO screening

Mapped pilot objective:

- Description of the variation between Trusts in respect to clinical workload and resources associated with implementing routine PO screening as a new screening test carried out on newborns

When considering the findings from the NIPE SMART derived activity data it is important to consider two separate concerns.

1. was any pulse oximetry screening achievable?
2. was pulse oximetry screening within the pilot screening pathway achievable?

The pilot screening pathway was developed by the NPSOP Project Board as an aspirational target. The view of the Board was that screening within 24 hours was the most potentially beneficial; however screening within 12 hours offered the most benefit. In order to try to achieve this, the relatively tight timeframe of 4-8 hours was agreed in the knowledge that this would encourage Trusts to screen early but may not always be clinically achievable. The findings presented from the data collated from the NIPE SMART IT system has highlighted the following clinical practice and workforce impact issues:

- A cohort of babies with no screening results recorded on the NIPE SMART system (i.e. no evidence of PO screening being achieved).
- Non-alignment to the pilot screening pathway (i.e. PO screening was achieved but not within recommended timings)

Reasons for these are highlighted below.

No results recorded on the NIPE SMART IT system

As detailed in the NIPE SMART PO activity data coverage section there was a cohort of babies with no results recorded on the NIPE SMART IT system. After discussion with the relevant PO pilot clinical leads and screening midwives in the Trusts the following possible causative factors emerged:

1. The PO screen could have been missed (not performed) and not recorded as such on the NIPE SMART system
2. The PO screen may have been performed but the result not entered on the NIPE SMART system
3. The screening result was incorrectly entered at 'site' level on the system and not on the 'hospital' facility resulting in the entry not being saved to the NIPE SMART system
4. The PO tab on the NIPE SMART system was set up separately from the NIPE examination data entry tabs. If the NIPE examination was entered at the same time as the PO screening result the NIPE examination had to be saved first of all followed by the PO screen result. If this did not happen the PO screen result was not saved to the system.
5. In Trusts in both groups, a significant number of babies were discharged early to the community setting with the NIPE exam undertaken in the home. However the PO screen may not have been performed either in hospital or in the home environment.
6. PO screening was not performed prior to the early discharge home from the delivery suite
7. Babies admitted to the neonatal unit that would be exempt from PO screening were not entered on the NIPE SMART as 'non eligible'
8. Delays experienced by community midwifery teams in entering PO screening results undertaken at home due to access to NIPE SMART in the community setting.

Although in the whole cohort over 90% of eligible babies were successfully screened, eight Trusts experienced a large number of 'no results recorded' on the NIPE SMART system. Of these Trusts, four were in Group B of which two were the largest tertiary units; both had implemented the NIPE SMART system early in 2015 prior to the commencement of Phase 2 of the pilot; and one in Group A just prior to Phase 2. These Trusts are to be commended for their commitment and hard work in implementing both a new IT system and PO screening in a short period of time given the numbers of staff that required training both to undertake PO screening and input the screening results to a new screening management system. Such a large clinical service initiative would ordinarily take a significant period of time to implement and embed as routine clinical practice.

Following detailed discussion with relevant personnel (PO pilot Clinical Lead) in these Trusts, responses anecdotally confirmed that babies were being screened for PO but the results were not being entered on the NIPE SMART system for many of the reasons outlined above (see appendix 14 for letter template to Trusts).To test this hypothesis the eight Trusts were asked to retrieve and scrutinise the medical records of those babies born in the month of November 2015 and enter the results of those babies screened to the NIPE SMART. The Trusts responded very well to this request and this showed that screening was being undertaken but not entered

onto the NIPE SMART system in many cases. The cohort number for these non NIPE SMART recorded screens reduced further over the latter course of the pilot.

There were examples of good practice amongst the Trusts in addressing this issue at local level. A common practice became established in three Trusts to reduce both the number of babies that missed screening and those with no results entered with the use of an alert sticker system on the labour ward. Other Trusts already had this process in place. If an early discharge occurred the PO screen would be performed and the result documented on a sticker and then stored in the baby's medical records. The result could then be entered independently on to the NIPE SMART or at the time of the NIPE examination. This system was also used as a process of communication with the postnatal ward staff to reduce the risk of the screen being missed.

One large tertiary Trust appointed a 'Newborn PO Champion' who supported staff on the postnatal wards and community with the input of PO screening results to the NIPE SMART and to deal with any clinical queries or issues arising with the pilot. This model helped significantly reduce the number of babies with 'no screening results' for this Trust.

Another Trust highlighted the issue of NNU admissions and the 'non-eligible' status not being recorded on NIPE SMART. The PO Clinical Lead informed the PO pilot team that local numbers of newborn admissions > 34 weeks gestation were around 12 babies per month over the 6 month period of the prospective phase of the pilot. This Trust had two hospital sites participating in the pilot hence the potential that 160 babies from the 'no results recorded' cohort were NNU admissions. It can be taken from this example that this situation was probable for all the participating Trusts.

All the pilot Trusts, with one exception, embraced the opportunity to commence PO screening in the community setting (usually after home birth) as part of the pilot or further develop existing services. However, one Trust had delayed the start of community screening due to a phased training programme whilst implementing the PO screening service. One Trust in Group A did not wish to offer PO screening in the community as part of the pilot due to the large geographical area covered by the community midwifery teams and the logistical issues this would cause with local training of such a large team for the purposes of the pilot.
All of the above required investigation at local level to identify the cause of the problem. All the issues raised warrant consideration in respect to clinical workload planning that would involve the screening midwife or a designated individual to monitor and investigate babies with no screening results recorded on the NIPE SMART.

NIPE SMART IT functionality issues

Some trusts in both Group A and B experienced difficulties with the entry of PO screening results. One area of concern related to the PO screen result entry being made at the same time as the NIPE examination result. Both tabs were set up independently of each other on the system to allow for different health care professionals (HCPs) to enter PO screen results and NIPE examination data. If entering both results together the NIPE examination result had to be entered and saved before entering PO screening results. This led to PO screening results not be saved to the system and contributing to the number of babies with no results recorded on the system. With local training and raising awareness this issue resolved over time as the pilot progressed.

A differing HCP to the PO screener entering screening results for both NIPE and PO was a clinical service model used by some trusts. This model created a couple of issues. Poor communication featured as a theme from the NIPE SMART ‘deviation from pathway’ reasons and reasons why the screen was not done. An example being a missed repeat screen being detected at the time of the NIPE examination where another HCP had performed the first screen. Some Trusts chose to limit the number of staff entering PO screen results on the system to negate the need to train many staff on the NIPE system as well as to perform PO screening. This model also creates governance issues. The ideal scenario should require the PO screener to enter the screening result on the NIPE SMART or equivalent HIS in a contemporaneous manner.

Some PO screening results from a few Trusts were entered incorrectly on the ‘site view’ instead of ‘hospital view’ on NIPE SMART. Again this lead to PO screening results not being saved in the correct part of the system. These results then had to be removed from the ‘site view’ by Northgate Public Service UK (NPS) and recorded again at local level. This process although completed in all cases, was time consuming. However, with additional local training and vigilant monitoring by screening midwives this issue resolved over the period of the pilot.

There was some evidence of miscategorisation of data fields arising from the use of the ‘deviation from pathway’ data field options. There were a number of babies who should have been changed to ‘non-eligible’ for screening in preference to some of the categories selected.

Non-alignment to the pilot screening pathway

The NIPE SMART PO coverage data has shown non-alignment with the pilot pathway for several Trusts. The main reason cited on the NIPE SMART 'deviation from pathway' categories was made for 'routine practice'.
Despite discussions with the pilot team, three trusts in Group A did not change from their established local PO screening pathway to the PO pilot screening pathway. This resulted in very early routine screening (under 4 hours) for one Trust or late screening for two Trusts. PO screening in one Trust was undertaken by the hearing screeners with screening undertaken in 9am –5pm hours. This service model resulted in later PO screening beyond 12 hours to the first PO screen.

Other reasons for deviation from pathway entries on NIPE SMART

Although 52% of all babies received PO screening within the suggested time of 4-8 hours, 78% within 12 hours and 92% within 24 hours, there were a significant number of entries on NIPE SMART under the 'deviation from pathway' data fields related to staffing and time constraints. The NIPE SMART was designed to flag up any deviation (however minor) from the pathway and staff were prompted to enter a reason for this. It was not possible to determine the exact timing of lateness of the screening results (e.g. the first PO screen may have been performed a few minutes over the recommended 4-8hr timing). The result would then fall into the 8-12hr timing interval. However, the results from the face –to- face post pilot questionnaires does provide some insight to the staffing issues experienced by some Trusts. These findings do indicate that adherence to the pathway has some impact on the clinical workload. However overall screening rates indicate the PO screening was achievable.

Learning points from workforce issues

The workforce impact and clinical workload issues highlighted the following learning points:

- when implementing PO screening ,Trusts need to consider a workforce planning initiative to ensure a robust screening pathway and referral process in which all eligible babies are screened and screening results are entered on the NIPE SMART or equivalent HIS
- consideration should be given to a local training needs analysis ensuring an appropriately trained workforce to meet implementation needs.
- consideration should be given to how the PO screening results are recorded in a contemporaneous manner or a robust process if not entered to the NIPE SMART or equivalent at the time of screening e.g. results recorded manually in case notes

- governance issues should be considered when transposing screening results from medical records to NIPE SMART.
- a relaxation of the tight timeframe for first screen to within clinically acceptable alternative parameters may reduce many of highlighted workforce issues
- a national recommendation or standard may encourage non aligning trusts to reconsider their local pathway and redesign their service model accordingly.

Non-NIPE SMART Trust coverage data

One pilot Trust had not engaged with the use of NIPE SMART due to the local implementation of new the EPIC hospital IT system. However, this Trust aligned the dataset from the NIPE SMART PO data fields to their new local hospital information system (HIS) to enable the collation and submission of the data requirements for the pilot. However, not all of data fields could be programmed to the local HIS including the repeat screen timing.

In this Trust a total of 2,758 babies were eligible for newborn PO screening in this period. The overall coverage for PO screening from the eligible cohort was 98.7%. A total of 2,688 babies had a negative screen result with 35 screen positive results. The screen positive rate for this Trust is 1.28% which is an outlier alongside another 3 Trusts with a screen positive rate over 1%.

Table 25 provides a flowchart summarizing the non NIPE SMART Trust data
A breakdown of the timing of the PO screening is provided in this Trust's report. A median 49.4% (n 1349) for screens being conducted at between 5-8 hours of age was followed by 14.5% (n 396) at 9-12 hours of age as indicated in Table 26. Notably 11.4% (n 313) of screening times were not entered into the local HIS. In addition the location of the screen was not entered in 11.4% of entries. This would suggest that the local HIS could not be programmed to automatically populate the time of the first screen as would the NIPE SMART system.

Table 25: Non NIPE SMART Trust data flowchart 1st July-31st December 2015

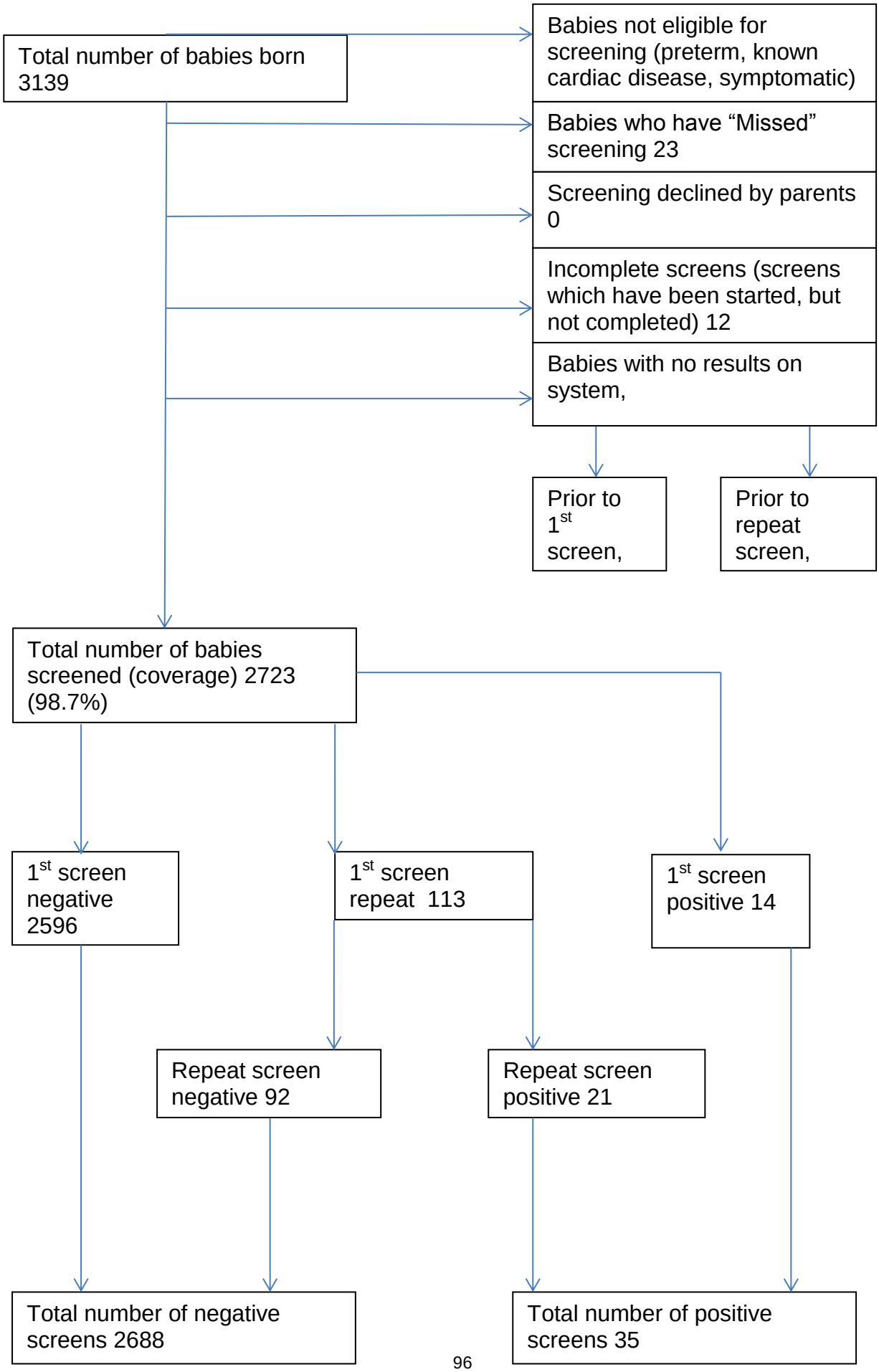


Table 26: Non NIPE SMART Trust 'age at screen'

Non NIPE SMART Trust Age at screen													
0-4 hours		**5-8 hours**		**9-12 hours**		**13-18 hours**		**19-24 hours**		**>24 hours**		**Not recorded**	
n	%of eligible babies	n	%of eligible babies	n	%of eligible babies	n	%of eligible babies	n	%of eligible babies	n	%of eligible babies	n	%of eligible babies
301	11%	1349	49%	396	15%	184	7%	84	3%	106	4%	313	11%

Note:

% denominator = total number of first screens (n 2733)

This does evidence only part alignment to the screening pathway. A breakdown of reasons for non-compliance with the screening pathway are included in Table 28

Table 27: Non NIPE Trust deviation from screening pathway timing data

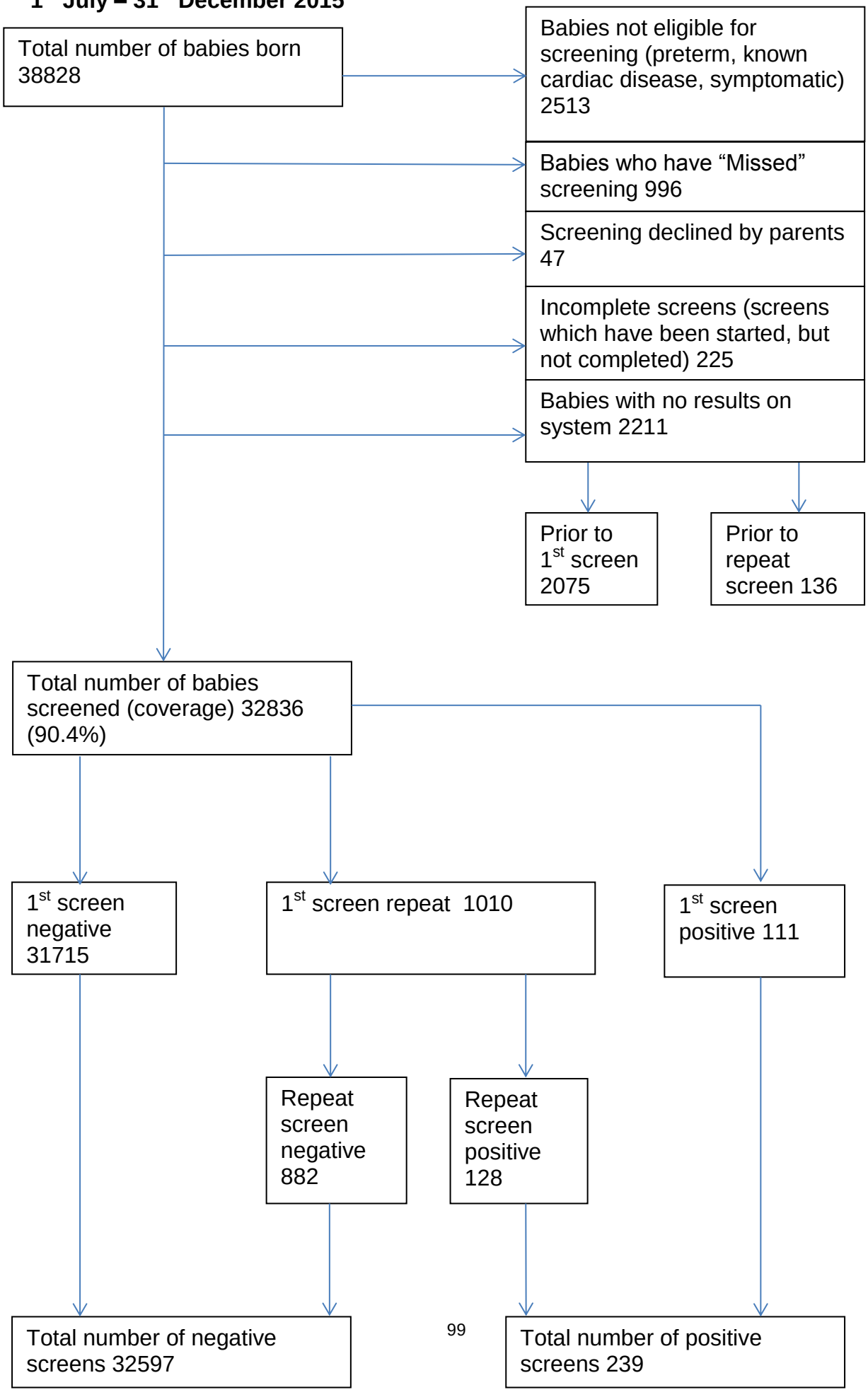
Deviation from screening pathway	n
Early discharge	142
Time	101
Staff	332
Equipment	10
Home birth	3
Mother and baby unavailable	4
Trust practice	225
No reason	131
Other	154
Total	**313**

It is also notable that the main reason for deviation from the recommended timing of the first screen on the screening pathway was staff availability related followed by routine Trust practice.

The overall incidence of screening pathway deviation was 40% (n 1102).The list mirrors that of the drop down menu option on the NIPE SMART for ‘deviation from protocol’. The non-NIPE Trust is in Group A giving an early indication that change to the screening pathway does incur a challenge for a Trust that has an established PO screening service provision.
However, it is clear that, similar to the NIPE SMART units the majority of babies (75%) were screened within 12 hours and only 4% were screened after 24 hours

Table 28 represents a flow diagram of the combined NIPE SMART data and the non-NIPE Trust data. This combined data gives an overall PO screening coverage rate of 90.4% as indicated in the flowchart. There was no expected PO screening coverage threshold set for the pilot. However, the only comparative in respect to any possible future coverage would be to that of the current NIPE Screening Programme with an acceptable screening coverage threshold of 95% of the eligible population.

Table 28: Combined data from NIPE SMART and non-NIPE SMART Trusts 1st July – 31st December 2015



Home PO screening

An important part of the pilot was to understand the number of babies that received PO screening in the home environment and to capture the timing of screening data in order to inform any practice models. In addition, these data would provide details of transport arrangements necessary for those babies with a positive screen requiring transfer to the main maternity unit. The cohort of home screened babies are those that were a home birth or have been an early discharge from hospital where the PO was not performed prior to discharge.

From the NIPE SMART PO data a total of 242 babies (0.72%) received PO screening in the home environment. Home screening numbers ranged from 1 to 47 in the individual pilot Trusts over the Phase 2 period of the pilot.

Most pilot Trusts wished to utilise the pilot to introduce or expand PO screening in the home environment. PO screening in the home environment appeared to be feasible as part of the pilot. As previously discussed the main problem was entering of the PO screening result on to the NIPE SMART system as the community midwives in many of the Trusts were not hospital based. This resulted in the late entry or non entry of the PO screening results to NIPE SMART.

Table 29 details the number of home PO screens performed during Phase 2 of the pilot. The number is also expressed as a percentage of each Trusts total number of PO first screens performed as the denominator. The data provided is collective from each Trust i.e. combined site data from Trusts with multiple sites.

Table 29: Combined NIPE SMART and non NIPE SMART PO home screening numbers

Trust	Nos. of home PO screens	Median time of 1st PO screen (hrs of age)
Bradford Teaching Hospitals NHS FT	9 (0.33%)	3
Cambridge University Hospitals NHS Trust	12 (0.4%)	n/a
Countess of Chester NHS FT	22 (1.48%)	4.5
Norfolk and Norwich University Hospitals	17 (0.73%)	8
Northern Lincolnshire and Goole Hospitals FT	6 (0.45%)	26
The Royal Wolverhampton Hospitals NHS Trust	0 n/a	n/a
Warrington & Halton Hospitals NHS FT	47 (3.46)	24
Brighton and Sussex University Hospitals	24 (0.99%)	17
East Cheshire NHS Trust	1 (0.12%)	2
Hull and East Yorkshire Hospitals NHS Trust	34 (1.26%)	22.5
Liverpool Women's NHS Foundation Trust	23 (0.6%)	6
United Lincolnshire Hospitals NHS Trust	9 (0.37%)	21
University Hospitals Of Leicester	17 (0.46%)	2
Wye Valley NHS Trust	9 (1.1%)	18
York Teaching Hospital NHS FT (including Scarborough General Hospital)	24 (1.04%)	4

The home PO screening in the Group A Trusts reflects the PO screening in the respective hospital settings. The median time to the first screen is also provided in Table 30. One Trust performed early PO screening in the hospital and has done so in the home. Two Trusts performed home screening within the recommended screening pathway time to first screen with two Trusts performing the first screen out with the screening pathway which is consistent with their hospital screening models. It cannot be determined from the NIPE SMART data report which of the home PO screens was home births. It is likely that the early PO screens indicate a home birth with the first PO screen being performed before the midwife left the home. The late PO screens have coincided with the NIPE examination in the home. This model may reflect

early discharges from the labour ward before the PO screen and NIPE examination was performed.

The Trust that did not want to offer PO screening in the home environment as part of the pilot did in fact undertake screening in the home.

In the Group B Trusts two performed early PO screening in the home with a median time to first PO screen of 2 hours. Two Trusts performed the first PO screen with a median time within the screening pathway recommended time. Four Trusts had a median time of over 12 hours. The late first screen again may indicate a model of PO screening with the NIPE examination in the home.

There were six repeat screens performed. The time to repeat screen ranged from three to over 4 hours (Time between first and repeat screens (within hour).

Homebirths with a PO screen positive outcome

There were five PO screen positive cases in the home environment screened cohort. Of the five cases three were planned homebirths accounting for 1% of the screen positive cases overall. One of the two unplanned births one had the PO screen performed in the home with the first screen performed at 5 hours of age. The baby was transferred by paramedic ambulance with mother. The baby was for a repeat PO screen and review in the main maternity unit. The baby was seen be a senior paediatrician but not admitted to the neonatal unit . No investigations were performed and no diagnosis provided other than ‘treat as normal’.

The remaining unplanned home birth was transferred to the main maternity unit and the PO screen performed in hospital. The first PO screen outcome was a direct referral, the baby was seen by a senior paediatrician, chest x-ray performed, blood tests taken – blood gas, blood cultures, C reactive protein (CRP) full blood count (FBC). Antibiotic therapy was given with a diagnosis of TTN requiring oxygen therapy. The length of stay on the neonatal unit for the baby was 96 hours (see screen positives data findings section).

Of the planned homebirths with a screen positive outcome two of the three cases were not admitted to the neonatal unit. One baby was seen by a senior paediatrician. Only a FBC was performed with no other investigations undertaken. Transitional circulation was diagnosed. The baby was discharged home. Another baby in this group was transferred with the mother by paramedic ambulance as the mother required medical attention. The baby was reviewed by a junior doctor. The first PO screen was performed at 4 hours of age with the repeat at 7 hours of age performed by a junior doctor. Admission to the neonatal unit was not required, no investigations performed and a diagnosis of hypothermia was made and transitional circulation. The baby was deemed otherwise well.

There were very limited data submitted for the remaining baby in the planned homebirths group as the baby was transferred into the community under the care of the GP. The NIPE examination was performed by the GP with the PO screen being performed by the midwife. The first PO screen was performed at 21 hours of age with the repeat at 23 hours of age. The baby was screen positive from the differential and did not require a direct referral at the time of the first or repeat PO screen. Both the maternal and baby medical records were not available to the data reporter hence the lack of data. It cannot be established from the data submitted if this baby was admitted to hospital for review.
No echocardiograms were performed in the home birth group.

Table 30: summarises the home birth data from the PO screen positive outcome cases:

Table 30: Home birth screen positive outcomes

Case no.	Home birth planned	Home birth unplanned	Admitted to the NNU	1st Screen performed in home	1st PO screen (hrs of age)	Repeat PO screen (hrs of age)	Diagnosis
1	yes	n/a	no	yes	2 hrs	6 hrs	Transitional circulation
2	yes	n/a	no	yes	4hrs	7hrs	Cold baby, poorly perfused feet
3	yes	n/a	n/a	yes	21hrs	23hrs	Transitional circulation
4	n/a	yes	yes	no	7 hrs	n/a	TTN requiring o2
5	n/a	yes	no	yes	5hrs	7 hrs	'Treat as normal'

In summary three Trusts performed early PO screening in the home with a median time to first screen of under 4 hours of age. Four Trusts had a median time to first screen of between 4-8 hours with six Trusts performing late PO home screening with a median time range of 17 -26 hours. The median time overall was 13 hours to the first PO screen. From the data presented PO screening in the home environment appeared to be feasible as part of the pilot. However, some community midwifery staff did experience delays with the entering of the PO screen on to the NIPE SMART due to the logistics of not being hospital based. It could not be determined how many of the home PO screens were in the 'no results recorded' on the NIPE SMART cohort.

Summary of NIPE SMART and non-NIPE SMART data findings section

The key findings from the NIPE SMART and non NIPE SMART Trust data can be summarised as follows:

- The overall coverage of PO screening for the period of the pilot was 90.4% with a total of 32,836 babies screened. A total of 32,597 babies had a negative screen result and 239 had a positive screen result

- In the Group A Trusts 3 out of 7 Trusts did not change their existing PO pathway to accommodate the pilot pathway in relation to the recommended timing to the first PO screen. In this group the remaining 4 Trusts had a predominant number of first PO screens performed at 4 -7 hours

- A total of 6 Trusts of the 8 Trusts in Group B had a predominant number of first PO screens performed at 4-7 hours. One Trust in Group B had a routine practice of the hearing screeners performing the PO screen as indicated with the timing to first screen 12-17 hours and 18-23 hours on each Trust site

- A total of 10 out of the15 pilot Trusts had the majority of first PO screens most within 4-7 hours

- Overall 76% of all first PO screens were performed within the first 12 hours

- The evidence presented suggests that discharge was not significantly delayed as a result of PO screening. This was applicable to the repeat screens only with some miscategorisation of the drop down options for reasons for delayed discharge

- There is evidence of miscategorisation of drop down menu options and misunderstanding of the screening pathway resulting in a number of inappropriately assigned circumstances entered on the NIPE SMART system. It is suspected that these anomalies were entered to the system early in the pilot but this cannot be validated nor the date extracted from the NIPE SMART final pilot report.

Phase 2 implementation prospective data findings (screen positive cases)

Mapped pilot objective:

- Audit screening outcomes in all eligible babies: all cardiac diagnoses, non-cardiac diagnoses in screen positive babies, referrals after a positive cardiovascular screen following NIPE or PO, deaths within 1 month of birth, through the collection of data and analysis

The data finding s presented in this section are mapped to the pilot objective above.
The Phase 2 data collection and screening pathway implementation of the pilot commenced on the 1st July and continued until the 31st December 2015. During this period, Group A Trusts were requested to align with the pilot screening pathway and Group B Trusts commenced newborn pulse oximetry screening. All PO screening results required entry to the NIPE SMART system or the EPIC (HIS) for the non-NIPE SMART Trust.

The Phase 2 data collection process also included the submission of a completed Excel spread sheet with the screening outcome within a defined dataset for each screen positive case. The aim of this pilot phase was to determine the number of referrals and admissions to the neonatal unit after PO screen positive result, the subsequent investigations, management and any referrals to regional paediatric cardiac centres with a cardiac diagnosis. A secondary aim was to identify those screen positive cases with a non-cardiac diagnoses detected through PO, investigations, results of referral.

There were a total of 239 screen positive cases from the total cohort screened (n = 32,836) with an overall screen positive rate of 0.73%. A total of 204 screen positive cases were recorded using the NIPE SMART system. The NIPE SMART data fields were mapped directly to the screening pathway in order to collate all direct referrals (positive screen) for senior paediatric review on the first pulse oximetry screen and all screen positive outcomes from the repeat screen. The confidential ID numbers from the NIPE SMART system were provided to Trusts within the activity reports to aid local identification of cases. The confidential ID number is only applicable for use on the NIPE SMART system and is of no identification consequence out with the system. The non NIPE SMART Trust reported 35 screen positive cases. Of the 15 participating pilot Trusts one Trust had no screen positive cases identified during the pilot period.

The completed Excel submission response rate from the Trusts was 97% (n 231). Of the eight outstanding cases to be reported four cases were data anomalies with false screen positives identified by the NIPE SMART system as 2 cases occurred in the same Trust. One of these cases involved transcription error with incorrect PO screen data being entered on the Excel

spread sheet. The Trust did not resubmit a corrected spreadsheet. For the remaining 2 cases an investigatory process was carried out to rule out transcription error and cross reference confidential ID numbers. One other Trust did have one case of a false screen positive case identified on NIPE SMART that resulted from a systems bug and subsequently removed from the Trust's overall screen positive number. The outcome data are presented on the 231 babies for which data were available.

Table 31 below details the number of screen positive cases for each Trust and the overall screen positive rate. The total number of completed screens in each respective Trust is the denominator. The percentage of screen positives that were admitted to NNU was also calculated:

Table 31: Newborn pulse oximetry screen positive rates by Trust

Trust name	Pilot Group	Number of screen positive cases	Screen positive rate (%) (Admitted to NNU %)	Total number of completed screens (denominator)
Bradford Teaching Hospitals NHS Foundation Trust	A	15	0.56% (0.26%)	2672
Cambridge University Hospitals NHS Foundation Trust	A	35	1.28% (0.66%)	2728
Countess of Chester Hospital NHS Foundation Trust	A	7	0.47% (0.27%)	1477
Norfolk & Norwich University Hospitals NHS Foundation Trust	A	10	0.43% (0.25%)	2320
Northern Lincolnshire and Goole Hospitals NHS Foundation Trust	A	3	0.22% (0.07%)	1334
The Royal Wolverhampton Hospitals NHS Trust	A	27	1.3% (0.81%)	2075
Warrington and Halton Hospitals NHS Foundation Trust	A	0	n/a	1344
Brighton & Sussex University Hospitals NHS Trust	B	10	0.41% (0.25%)	2407
East Cheshire NHS Trust	B	3	0.35% (0%)	836
Hull & East Yorkshire Hospitals NHS Trust	B	6	0.22% (0.1%)	2675
Liverpool Women's NHS Foundation Trust	B	52	1.37% (0.68%)	3790
United Lincolnshire Hospitals NHS Trust	B	6	0.24% (0.12%)	2423
University Hospitals of Leicester NHS Trust	B	34	0.92% (0.24%)	3684

Wye Valley NHS Trust	B	5	0.62% (0.49%)	804
York Teaching Hospital NHS Foundation Trust	B	26	1.14% (0.44%)	2271

There are four Trusts that are outliers with a screen positive rate more than 1%. In three of these Trusts each had a CCHD case detected through pulse oximetry screening. When the admission to NNU rate is calculated it can be seen that the outlier status becomes less prominent. The unit with the most admissions (Liverpool Women's Hospital) had 26 admissions over the six month period which equals one admission per week.
Figure 16 provides a flowchart overview of the screen positive data outcomes.
Of the 239 babies with a positive test result data was received on 231.
There were 14 diagnoses of CHD - including 8 CCHDs and 1 serious CHD and 4 significant CHDs (see figure 16 and tables 37 and 38). Of the remaining 225 screen positive babies 86 (36% of total screen positives) had a significant non-cardiac condition –mainly respiratory or infective conditions which required treatment. (See figure 16 and table 40).
135 out of 239 (56%) had transitional circulation which is a physiological condition requiring no specific treatment – i.e. the babies with this condition are healthy.
Of the 135 babies with transitional circulation only 22 (16%) were admitted to NNU and the rest remained on the postnatal ward with the mother (see figure 17).

Delay in discharge for screen positive babies

Of the 239 screen positive babies discharged was not delayed in 115 (48%). Discharge was reported as delayed in 68 (28%) but of these, over half (53%) had a significant clinical diagnosis which is highly likely to have delayed discharge anyway. Overall, discharge was reported as inappropriately delayed in 32 babies (13% of all screen positives). These babies all had transitional circulation (see figure 18).

Admission to NNU and investigations

A total of 115 out of 239 (48%) of the screen positive babies were admitted to NNU and 96 (84%) of the babies admitted had a significant condition which required on-going treatment (see figure 17).
Two babies with culture negative sepsis were not admitted to NNU and were managed on the postnatal wards; the rest of the screen positive babies who were not admitted had transitional circulation.

Senior paediatric reviews

A total of 184 (80%) of screen positive babies were reported to have been seen by a senior clinician. Of those screen positive babies recorded as not seen by a senior paediatrician five were admitted to the NNU, one of which was on the NNU for a few hours observation only. Four babies were reviewed by a junior doctor. Ten babies from one Trust were not seen by a senior paediatrician and no details provided of a junior doctor review. However, on discussion with the PO Clinical Lead for this Trust it was confirmed that the medical records of this group of babies were reviewed by a consultant neonatologist. One baby was reviewed by an ANNP. One Trust acknowledged in one case no evidence in the medical records of a senior paediatric review therefore violating local guidance. The remainder of cases no additional information was provided therefore unable to determine if the baby was seen by a junior doctor.

A senior paediatrian review for a PO screen positive outcome is a pilot screening pathway recommendation. The screen positive babies who were healthy and not reviewed by a senior paediatrician may be of significance in relation to the screening pathway and merits further consideration. It could not be determined if those babies not seen by a senior paediatrician had any workforce implications.

Level of support and investigations in screen positive babies admitted to NNU

The majority (56%) of screen positive babies who were admitted to NNU stayed for 48 hours or longer. 19% stayed less than 12 hours (the 22 babies with transitional circulation, see figure) and 30% stayed less than 24 hours (see table 33).

Figure 15: PO screen positive outcomes

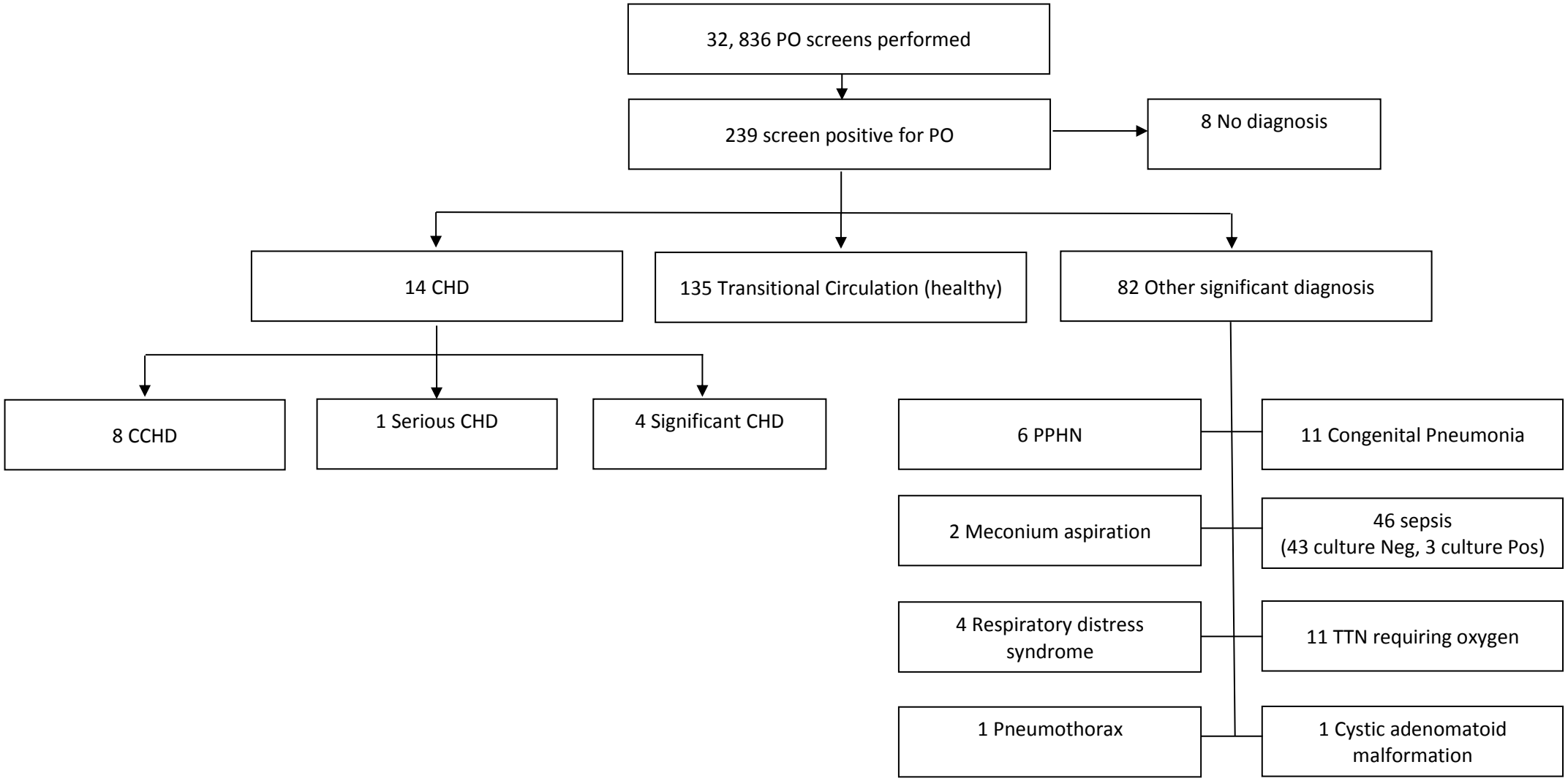
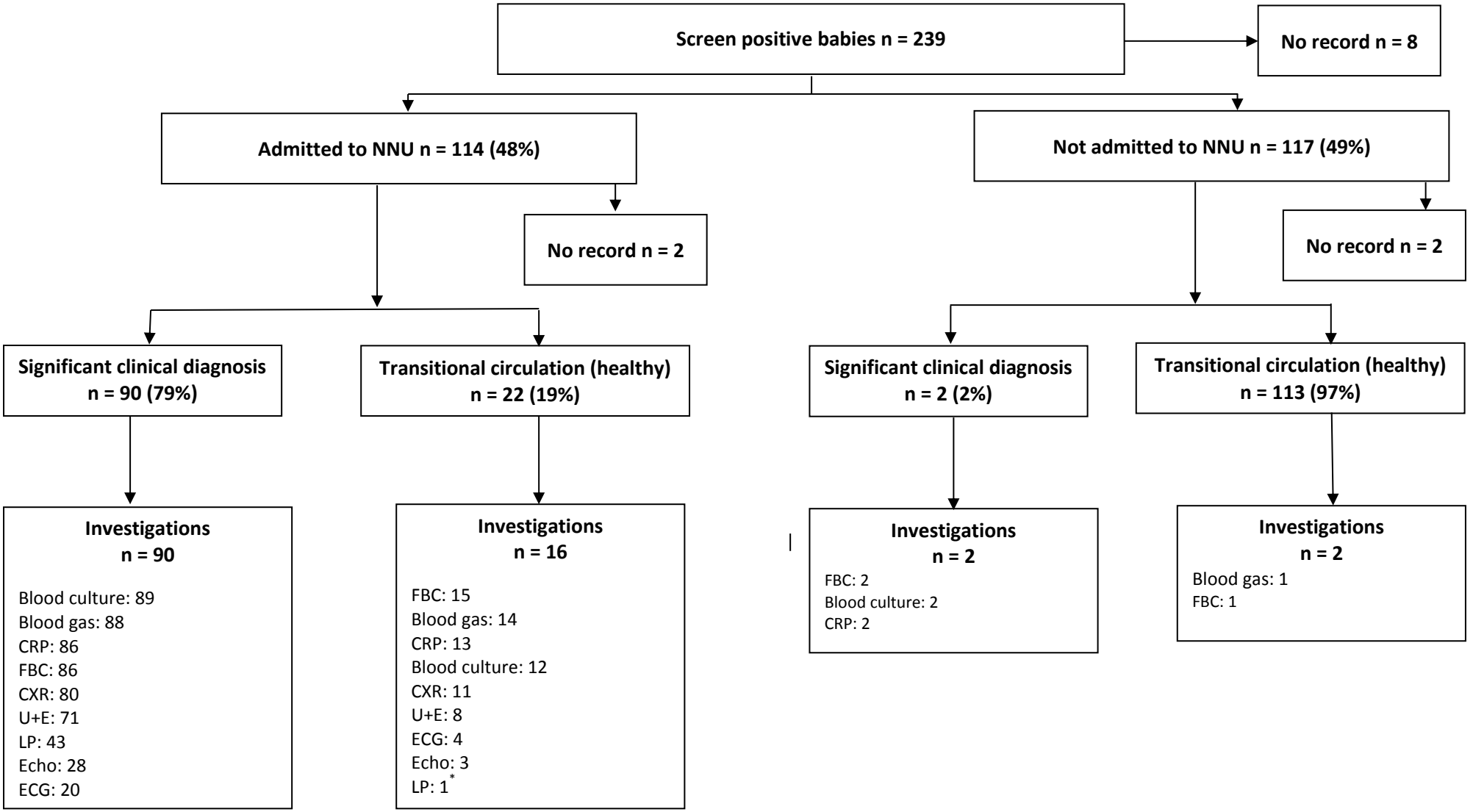


Figure 16: PO Screen positive babies – management and investigations



*** LP was only investigation which suggests this was recorded in error.**

Table 32: Admissions to NNU (n=114). Length of stay

Length of admission	
<12 hours	21 (19%)
12-24 hours	13 (11%)
24-48 hours	11 (10%)
48-72 hours	17 (15%)
>72 hours	47 (41%)
Not documented	5 (4%)

47% of admissions required intensive or high dependency care. 18 babies (16%) required some form of positive pressure respiratory support – the majority of these (10 babies) required CPAPor BiPAP but 6 babies received mechanical ventilation. (see tables 34 and 35)

Table 33: Levels of care (maximum level)

Intensive care	27 (24%)
High dependency	26 (23%)
Special care	61 (53%)

Table 34: Maximum level of respiratory support

Additional oxygen required	58
Ventilatory assistance total	18
CPAP/BiPAP	10
Conventional ventilation alone	5
High flow oxygen	2
Conventional plus Nitric Oxide	1

58 babies (51% of admissions) required additional oxygen therapy.
102 (89%) of babies admitted were started on antibiotics and 11 were started on a prostaglandin (Prostin) infusion prior to cardiac assessment by echocardiography (see table 35).

Table 35: Additional treatments

Antibiotic therapy	102
Surfactant therapy	3
Prostin infusion	11

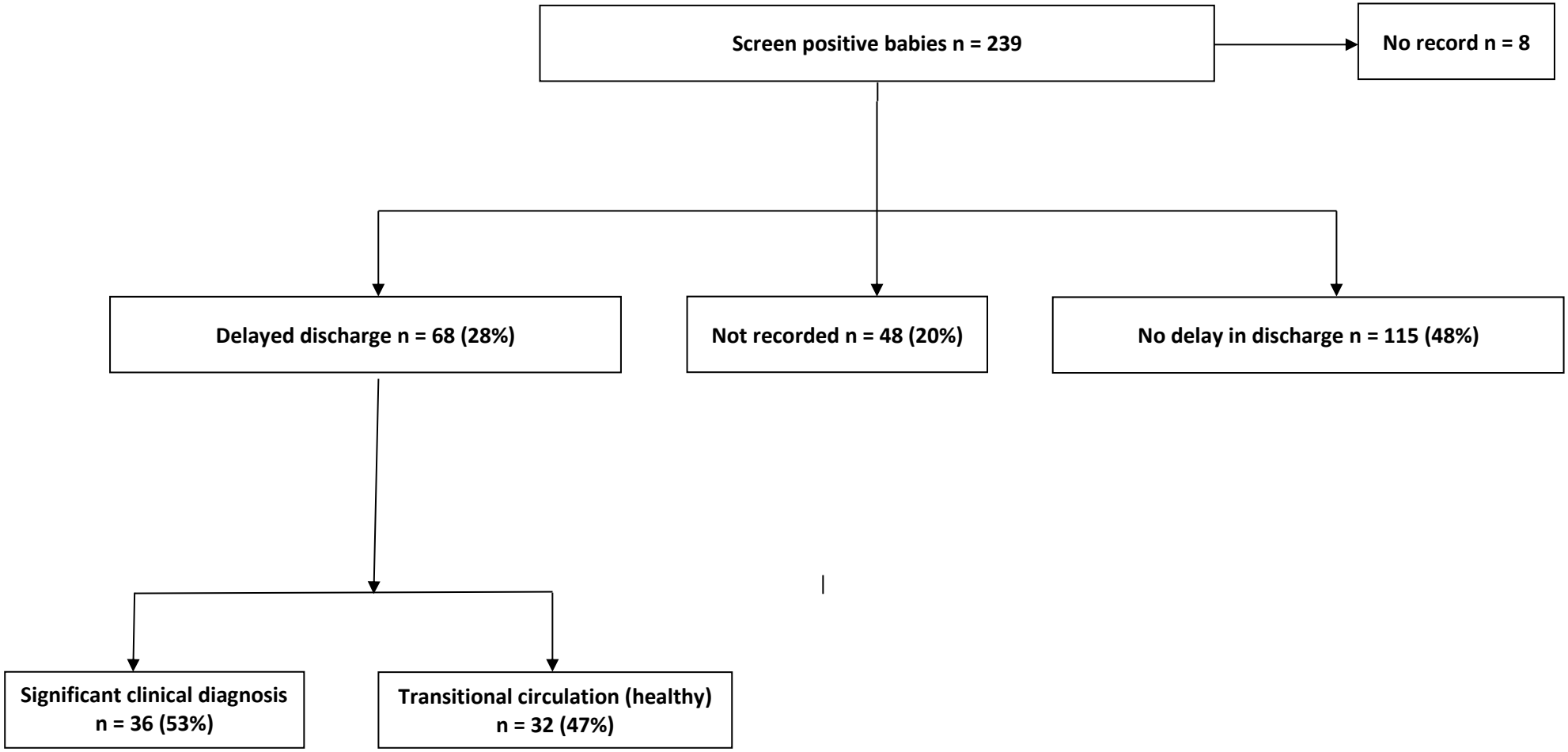
Investigations on screen positive babies

110 (46%) screen positive babies underwent clinical investigations the vast majority of (106; 96%) were those admitted to NNU (see figure 17).
Four babies who were not admitted also had blood tests only.
The investigations can be categorised as routine blood testing (full blood count [FBC], C-reactive protein [CRP], urea and electrolytes [U+E] and blood gas), radiography (chest x-ray [CXR]), investigations for suspected sepsis (blood culture, lumbar puncture) and cardiac investigations (ECG and echocardiography).

Most babies who were admitted (106/114; 93%) underwent some form of investigation - the most common being blood testing (88%) and CXR (80%).

Only 27% of screen positive babies underwent echocardiography (see figure 17 for full details).

Figure 17: PO screen positive babies – delay in discharge



Details of diagnoses for screen positive babies

Cardiac diagnoses

Eight Babies with CCHD were identified by screening (true positives). In addition, one baby with a serious CHD and four babies with significant CHD were also identified by PO screening.

Table 36: CCHDs detected from PO screening

CCHD's	Trust
Narrow aortic arch (IAA)	Cambridge University Hospitals NHS Trust
Critical pulmonary stenosis, VSD and PDA	Royal Wolverhampton Hospital NHS Trust
Critical pulmonary stenosis	York Teaching Hospitals NHS Trust (Scarborough General Hospital)
Critical pulmonary stenosis	Cambridge University Hospitals NHS TRUST
TGA with VSD	University Hospitals Leicester (Leicester Royal Infirmary)
TGA, PDA and mild heart dilation	York Teaching Hospitals NHS Trust (York Hospital)
Supracardiac TAPVD	Brighton and Sussex University Hospitals (Royal Sussex Hospital)
Hypoplastic aorta/coarctation (HLHS) and mixed TAPVD	Northern Lincolnshire and Goole NHS Foundation Trust (Diana Princess of Wales Hospital)

Table 37: Other CHDs detected from PO screening

Other CHDs	Number	Definition
PDA	**8**	Non-significant CHD
PFO	**6**	Non-significant CHD
VSD	**1**	Significant CHD
Right ventricular and septal hypertrophy	**1**	Significant CHD
Septal hypertrophy	**1**	Significant CHD
Enlarged heart, thickened ventricular septum with small pericardial effusion	**1**	Significant CHD
AVSD	**1**	Serious CHD

False screen negative results

Two babies with CCHD (false negatives) and one serious CHD (Fallot's tetralogy) were missed by PO screening (and by fetal anomaly screening and NIPE). One baby died and one presented in a collapsed state. The serious CHD presented with symptoms but did not require urgent treatment.

Table 38: False screen negative cases not detected by PO screening

CCHD Readmissions (False negative pulse oximetry screening result)	Trust	Additional comment
Coarctation of Aorta	Cambridge University Hospitals NHS Trust	Postnatal admission with collapse
Hypoplastic Left Heart Syndrome (HLHS)	Northern Lincolnshire and Goole NHS Foundation Trust (Diana Princess of Wales Hospital)	Neonatal admission - baby death

Non-cardiac diagnoses in screen positive babies

Transitional circulation

Of the 239 babies who tested positive, 135 (56%) had a final diagnosis of transitional circulation (i.e. healthy babies with no pathological condition). The vast majority (113 babies; 84%) of these were not admitted to NNU and following assessment were treated as normal on the postnatal ward and only 2 underwent investigation (see figure 17).
22 babies with transitional circulation were admitted to NNU, most (73%) underwent some form of investigation (see figure) but all were discharged within 12 hours.

Respiratory and infective conditions

Thirty-six babies had a significant respiratory condition (see figure 16) which required respiratory support (see table 35) and/or treatment. 46 had an infective condition – either culture-negative (43) or culture-positive (3) sepsis requiring 5 days of antibiotics (see table 40 for all definitions). One baby had a cystic adenomatoid malformation of the lung (congenital lung malformation).

It is possible that some of the babies who were diagnosed with congenital pneumonia or culture-negative sepsis were treated inappropriately – i.e. they did not have an infection - but it is very difficult to quantify this. In order to minimise this possibility we used definitions of sepsis

(see table) that were consistent with the NICE guideline on the management of early-onset sepsis (CG 149, 2012).

Hypoxaemia is one of the clinical indicators for EOS defined by NICE (but not a red flag indicator) and so by definition all screen positive babies had at least one clinical indicator. Our definitions also included raised CRP as defined by NICE.
The NICE recommendation for continuing antibiotics beyond 36 hours in a baby with a negative blood culture includes regular assessment including the level of initial clinical suspicion of infection, the baby's clinical progress and current condition, and the levels and trends of C-reactive protein concentration. We have made the assumption that these clinical guidelines were followed and therefore it seems unlikely that many babies were treated inappropriately.

Table 39: Definitions of non-cardiac diagnosis in screen positive babies

Congenital Pneumonia	Raised inflammatory markers (CRP > 10 mg/L) +/- positive culture, radiological changes on chest x-ray, oxygen requirement (for longer than 2 hours), antibiotics for ≥ 5 days
Meconium aspiration syndrome	History of meconium staining of liquor, respiratory distress, oxygen requirement (for longer than 2 hours), radiological changes on chest x-ray
Sepsis	Raised inflammatory markers (CRP > 10 mg/L) +/-positive culture, antibiotics for ≥ 5 days
TTN requiring oxygen	Tachypnoea with radiological changes of fluid retention, oxygen requirement (for more than 2 hours), no rise in inflammatory markers or positive culture

N.B. Congenital pneumonia, meconium aspiration syndrome or TTN requiring oxygen were classified as significant respiratory Illness

Workforce impact from PO screening screen positive outcomes

The PO pilot screening pathway recommended that all screen positive cases were seen by a senior clinician. This occurred in 80% of cases and this clearly had an impact on the clinical staff in the Trusts involved. Why the remaining 20% were not reported to have been seen by a senior clinician in line with the screening pathway is not clear, and is likely to be related to lack of availability or competing clinical demands.

The number of screen positive cases within Trusts ranged from 0 to 52 (mean 16) which equates to an average of approximately one screen positive case every 11 days. (range 0-2 per week). Of the screen positive cases, 48% were admitted to the NNU. This also will have an impact on the clinical workload, particularly the 22 unnecessary admissions who were healthy babies with transitional circulation. The data show that the majority of

babies who were admitted to the NNU had a significant illness which required treatment and it is likely that these babies would have required admission to NNU anyway regardless of whether screening took place or not. Of the screen positive babies, approximately half underwent additional investigations ranging from blood tests to X Rays and cardiac evaluations which has impact on clinical laboratory and allied health professional services. No further formal evaluation of the impact of screen positive cases was undertaken during the pilot. However, the data are available should a further health economic evaluation be considered. A broad overview of the impact of the clinical services was discussed with the clinical leads in each trust and is described in the post pilot questionnaire section.

Summary of screen positive results

The key points from this section can be summarised as follows:

- 239 out of 32 836 screened babies had a positive test (screen positive rate of 0.73%).
- Of these 114 (48%) were admitted to NNU.
- Eight babies had the target condition of CCHD but a further 88 screen positive babies had a significant condition which required treatment.
- In all, 135 (56%) of screen positive babies were healthy with transitional circulation but only 24 of these were admitted to NNU and/or underwent investigation. Therefore only 24/239 babies (10% of screen positives and 0.07% of all babies screened) were definitely inconvenienced (i.e. a healthy baby who underwent unnecessary admission and/or investigation) but importantly none was delayed longer than 12 hours.
- Two babies with CCHD were missed by all screening methods including PO screening. One of these babies died and one presented in a collapsed state.

Although the pilot was designed to establish feasibility rather than test accuracy the apparent sensitivity of PO screening this cohort was 80% with specificity of 99.2% which is consistent with published data on PO test accuracy.

Post Pilot Questionnaire Data Findings

Purpose of the semi-structured interview

The semi-structured interview proforma aimed to capture staff experiences in relation to the implementation of PO screening for the first time (Group B Trusts) or in changing from an existing screen pathway to the pilot pathway (Group A Trusts).

The interviews were undertaken following completion of the pilot and explored local expectations, experiences and service changes during the pilot period.

Objectives of the interview

A semi -structured interview proforma was developed to:

- capture the experiences of local Trust staff implementing the pilot
- understand any service changes during this period which might have an impact on the successful implementation of a new screening pathway
- gather additional information to understand any variation in Trust experiences or outcomes in relation to the pilot
- supplement existing feedback information gained through the Workshop event
- contribute to the 'Lessons Learned' from the pilot and inform decisions about national rollout.

Semi-structured interview method:

- Interview type: Semi -structured proforma
- Method of questionnaire administration: Face to face at local Trust level

Interviews with local Trust staff were performed by one member of the PO Project Board and NIPE Implementation Team who conducted face-to-face interviews using the semi-structured questionnaire format. The respondents were medical, nursing, midwifery and screening practitioners involved in the PO screening pilot.

The semi-structured questionnaire included the following sections:

1. Organisational changes (to identify significant changes during the pilot period)
2. Staff experiences with implementation of the new pilot screening pathway in relation to:
    a. Neonatal services provision
    b. Local newborn physical examination service provision (NIPE)
    c. Local newborn PO screening service provision
    d. Homebirths

3. Local management of paediatric cardiac referral processes following a positive screen
4. Education and training of staff involved in screening
5. Equipment provision to support screening
6. Parental responses to the pilot
7. Trust staff perspectives on the pilot.

Findings from the post pilot interviews

Response rates

All 15 pilot Trusts participated in the interviews and were visited in the immediate post-pilot period during January 2016. There were a total of 17 completed interviews as four Trusts had two maternity services within the Trust some of which had diverse application of the screening pathway. In each Trust, between one and eight staff members were interviewed. In 14 of the responses at least one paediatrician or neonatologist involved in the pilot was interviewed, while in the remaining three, an advanced nurse practitioner was a key respondent. Other staff who were interviewed included a combination of midwifery staff (nine Trusts), screening coordinators (six Trusts) and neonatal nursing staff (six Trusts).

Results from the interviews are described below.

Organisational changes

It was essential to capture any recent organisational changes that had occurred within participating pilot Trusts, which may have impacted upon the success of the pilot. A total of 3 Trusts (17%) described an organisational change. Two Trusts commented on the clinical changes required but this was a misinterpretation of the question. One Trust identified significant organisational change that was confirmed to be unrelated to PO screening. No Trust described organisational changes that were necessary for the successful implementation of the pilot.

Neonatal service provision

Questions within this section aimed to understand how the pilot Trusts managed babies that required a repeat PO screen and whether there were variations in practice from the screening pathway.

The repeat arm of the PO pilot screening pathway recommends that if either (pre- or post-ductal) readings for the first PO screen are 90-94% or a difference of 2% is recorded, then the baby should be reviewed by a health care professional and a repeat screen performed after two hours.

All Trusts were asked to describe the management of a repeat screen in babies who had a presumed positive screen result at the first screen. In all Trust sites the first screen was carried out by designated staff (including healthcare assistants/midwifery support workers, midwives or junior doctors or hearing screening staff).

In nine (53%) Trusts, a baby that required a repeat PO screen was reviewed by a senior clinician (paediatrician or neonatologist) after the first screen result, and in six of these sites a baby may be admitted to the neonatal unit for further investigations or the repeat screen. In eight (47%) Trusts, babies requiring a repeat screen were not seen by a senior clinician unless the repeat PO screen was positive. In these sites practice after the first screen varied: in two sites babies were seen by the paediatric SHO, in one site babies were admitted to the neonatal unit for observation pending the repeat screen, and in five sites midwifery and screening staff were made aware of the need for a second screen and the baby remained an in-patient until this was completed.

The staff member performing the repeat screen varied: junior paediatricians performed the repeat screen in four Trusts, a midwife repeated the screen in ten Trusts and the repeat screener was unspecified in three Trusts.

The senior clinician asked to review the baby after a repeat screen was a senior paediatrician in nine sites, a midwife in one site and an advanced nurse practitioner in one site (the senior clinical reviewer was unspecified in six sites.)

If babies were admitted to the neonatal unit, they were reviewed clinically, monitored and tests were performed if there were clinical indications.

Trusts who undertook PO screening prior to the pilot (Group A) were asked to comment on any change to the way the repeat screen was managed during the pilot. All eight Trust sites (100%) confirmed there was no change to the management, however staff in one site noted that a repeat screen was not part of the screening pathway prior to the pilot and one other site noted that the difference between pre- and post-ductal readings changed from 3% to 2% as a result of the pilot pathway being introduced (thus potentially increasing the number of babies who required a repeat screen).

There were other variations from the pilot screening pathway that occurred in individual sites:

- In one site, the repeat screen was usually performed before 2 hours
- For community births, the baby was admitted to hospital for the repeat screen
- In one site, a further PO measurement was sometimes requested after review by a paediatrician (this was described as a ‘third screen’ however it is not part of the screening pathway)

One site noted they performed the repeat screen after more than two hours when their unit was busier than usual.

It was important to capture staff perceptions of the pilot in each Trust about the impact of introducing PO screening on neonatal unit admissions. Trust staff were therefore asked if they had experienced a noticeable increase in admissions to the neonatal unit as a result of the pilot. The majority of Trusts (94%; n=16) were unaware of any increase in neonatal unit admissions as a result of the pilot.

One Trust had reportedly experienced increased admissions to the neonatal unit. One consultant considered suspending the pilot for two months when there was a shortage of neonatal cots. This Trust was a tertiary unit with a busy neonatal intensive care unit (NICU). The NICU was particularly busy at one point in the pilot with an overcapacity of neonatal cots. However, the rest of the consultant body decided that the benefits of PO screening outweighed the risks and continued with the pilot. This Trust also reported a higher than average number of PO screen positive cases but the actual number of babies admitted to the NICU from a PO screen positive outcome was relatively low at 0.68% of the total number of screen positive cases (see PO screen positives data findings section pg. 107). In addition, those babies not admitted to the NICU with a PO screen positive result in this Trust did have the medical records reviewed by a consultant neonatologist who agreed that admission to the NICU was not necessary.

Local newborn physical examination service provision (NIPE)

The aim of this section of the questionnaire was to capture any changes that had been made in pilot Trusts to the newborn examination (NIPE) in order to accommodate PO screening.

A total of seven (41%) respondents commented that they had changed the newborn physical examination (NIPE) service provision when introducing PO screening (including six Trust sites in Group B and one in Group A). However on further questioning it appeared that the key change for three Trusts was introducing the NIPE SMART IT system for recording NIPE exam results, while three further Trusts noted that the NIPE exam was now an opportunity for checking whether PO screens had been completed and recorded. Prior to the pilot, the Group A Trust performed the NIPE exam and PO screening at the same time, however the PO screen was subsequently undertaken earlier than the NIPE exam to conform with the timings recommended within the pilot screening pathway.

Reported adherence to the pilot screening pathway

Pilot Trusts were asked about their perceived adherence to the newborn PO screening pathway (attached as appendix 1). A total of 53% (n 9) respondents reported that they had adhered to the pilot screening pathway and four had trained additional staff to perform PO or had altered ward practices to ensure this was possible. One stated that they adhered to the pathway but might also have occasionally varied the timing of the screens.

The remaining eight (47%) of respondents reported that they did not always adhere to the pilot pathway; of these six did not consistently perform the first PO screen at 4-8 hours after birth, although two reported that screens were only delayed in a minority of cases. The two remaining respondents , which were in Group A, continued to perform the PO screen with the NIPE exam as they had done prior to the pilot, and stated that they had not amended their screening protocol to conform to the new pilot screening pathway. Staff in one of these Trusts noted that this was because they experienced difficulty with screening out-of-hours as they had no trained staff member available at this time.

Table 41 details Trust perceptions of adherence to the screening pathway as compared to actual adherence to timing of screens in line with the screening pathway. The mean timing data source is derived from the NIPE SMART national activity final report for the pilot period:

Table 40: Outcome responses to reported adherence with the newborn PO screening pathway

Trust name	Pilot Group	Reported adherence to newborn PO screening pathway	Reason for deviation from Screening Pathway	Mean time of 1st PO screen (hours of age)
Bradford Teaching Hospitals NHS Foundation Trust	A	No	Timing varied	4.3
Countess of Chester Hospital NHS Foundation Trust	A	Yes		12.6
Norfolk & Norwich University Hospitals NHS Foundation Trust	A	Yes		10
Northern Lincolnshire and Goole Hospitals NHS Foundation Trust	A	No	Done with NIPE exam – existing service model	20.3
The Royal Wolverhampton Hospitals NHS Trust	A	Yes	Done with NIPE exam	6.3
Warrington and Halton Hospitals NHS Foundation Trust	A	No	Done with NIPE exam – existing service model	30
Brighton & Sussex University Hospitals NHS Trust -	B			
Royal Sussex Hospital site		No	Timing varied	9.7
Princess Royal Hospital site		No	Timing varied	6.1
East Cheshire NHS Trust	B	Yes		9.6

Hull & East Yorkshire Hospitals NHS Trust	B	Yes		8.8
Liverpool Women's NHS Foundation Trust	B	Yes		9.6
United Lincolnshire Hospitals NHS Trust Lincoln County Pilgrim Hospital	B	No	Timing varied	 17.8 15
University Hospitals of Leicester NHS Trust Leicester General Leicester Infirmary St. Mary's Birth Centre	B	Yes		 18.9 6.8 5.4
Wye Valley NHS Trust	B	No	Timing varied	8.1
York Teaching Hospitals NHS Foundation Trust – York Hospital site	B		Also commented 'Time varied'	
Scarborough General Hospital site		Yes No	'Time varied'	4.5 2.9

The above table does not include the non-NIPE SMART Trust mean timings. The PO screening timings for this Trust are discussed within the NIPE SMART coverage section.

Recording screen results using the NIPE SMART or local IT system

Ideally screening results should be entered into the NIPE SMART or local IT system at the time of screening but this was not always achievable. A total of nine (53%) sites entered PO screening results into the NIPE SMART IT system at the time of the NIPE examination (which was performed later than the PO screen) and seven (47%) entered results at the time of PO screening (this included five sites in Group B, one site in Group A and one site using a local IT system). Staff on one site noted that they only managed to enter the screen result at the time of the screen in 25% of cases and mainly relied upon retrospective recording by neonatal nurses. Two sites used a sticker on the notes to designate which babies had been screened so the information could be added to the NIPE SMART system retrospectively.

In most sites (n 14), the screen results were entered by the staff member performing the screen. However it was noted that some screening staff could not access NIPE SMART and, in at least three sites, alternative systems for recording to ensure full coverage were required. In the analysis of screen coverage during the pilot, a higher than expected number of babies with no results recorded on NIPE SMART IT than expected. Trust staff were asked to review the notes for these babies and they reported that these were usually babies with screen results recorded in the notes but not entered into the NIPE SMART IT system. Table 42 details when the PO result was entered on the NIPE SMART

Table 41: Timing of when PO screen results entered on NIPE SMART

When the PO screening result entry made	n
When NIPE exam results are recorded	9 (53%)
At time of the PO screen	7 (41%)
Retrospectively by neonatal nurses	1 (6%)

Problems in accessing or using the NIPE SMART system were highlighted by several sites, including an unresponsive NIPE SMART helpdesk, insufficient local staff trained to use the system or designated as super-users able to resolve problems, no access for locum doctors who had transferred from other sites, difficulty in accessing the system from community laptops and prompts that were only helpful if results were being entered immediately after the screen. Two sites pointed out that there was nowhere to record who performed the screen and who was entering results if these were different. Finally one Trust that had newly implemented the NIPE SMART system commented that it was a positive addition to their screening processes.

Staffing

Trusts were asked if additional staff were required in order to offer PO screening. In Group A (PO screening already performed prior to the pilot) only one Trust stated that implementing the service had required additional staff. This increase was reported as the training of additional numbers of midwives to undertake PO screening and not the recruitment and employment of additional staff. The requirement to train additional midwives to undertake PO screening was to enable this Trust to change from their existing pathway to adhere to the pilot screening pathway recommended timings. All other Trusts did not require additional staff to undertake PO screening.

Trusts did emphasise the need to train additional staff to be capable of undertaking PO screening. Staff at one Trust specifically noted that they had been unable to implement PO screening out-of-hours at one site despite training additional healthcare staff, as they had insufficient staff overall to cover the additional screening workload. The training requirements for the implementation of PO screening are described with the Education and Training section (see pg. 127).

Although no Trusts required recruiting additional staff one Trust in Group B commented that they may recruit more nursery nurses in the future to undertake PO screening. in addition one site at this trust commented that only the nursery nurses and one midwife had been trained to undertake the PO screening and there wasn’t enough ‘super users’ for the NIPE SMART system to create passwords. The other Trust site commented that not all the midwives were trained to perform PO screening as the nursery nurses performed the screening. Issues arose if a paediatrician not available when a nursery nurse wasn’t available.

Home environment

Newborn PO screening was offered in the home environment by 16 of the 17 pilot Trust sites. One Trust did not offer screening in the home environment by community midwives due to the large geographical area and multiple community midwifery teams. This Trust considered that training such a large number of midwifery staff to perform the screen for the pilot was not logistically possible in the context of the pilot. However, the home PO screening data shows that this Trust did in fact undertake PO screening in the home.

Of the 16 responder sites offering PO screening for homebirths, two performed screening at two hours of age, one at five hours of age, five screened just before the midwife left the home (which was often before four hours of age), and one screened 'before 12 hours of age'. Four sites asked mothers to attend hospital for screening although one of these also offered PO screening as part of the NIPE exam if this involved a home visit. The timing of the screen was unclear in two sites.

Trusts were asked about any delay with entering data on the NIPE SMART system for homebirths. A total 11 (73%) respondents did experience a delay with screening entries and four (27%) did not (one Trust did not provide an answer). It was noted that many community midwives are not based in the main maternity unit resulting in a delay in entering data into all maternal and newborn information systems. Community midwives reported results by phone in three sites.

Local management of PO screen positive cases and paediatric cardiac referral and investigation

If a baby had a positive screen result, then they were referred in all cases. In 11 sites, babies who had a positive screen result were given a clinical examination by a senior clinician (six sites) or advanced nurse practitioner (one site) or unspecified clinician (four sites). The clinician performed further investigations that determined subsequent care. The decision to perform an echocardiogram was decided at local level. At least three sites were able to offer an echo locally while one transferred babies to the nearest cardiac centre. In six sites, babies were automatically admitted to the neonatal unit where they could be observed prior to clinical examination, further investigation or repeat screen.

No staff involved in the pilot was aware of a noticeable increase in requests for echocardiograms and cardiology consultations during the pilot period.

Education and training

Education and training was an important element of the pilot implementation process. The seven sites already performing PO screening (Group A) had training systems in place but also provided training updates to staff involved in the pilot. In one Group A Trust training was only required for the pulse oximeters used for the pilot as this differed from the model already in use for PO screening by this Trust. One Group A Trust as previously mentioned trained additional midwives in order to change from their established screening pathway to the pilot pathway. Two Trusts in Group A did not require the equipment training provided by the pulse oximeter manufacturer as the same model of equipment was already in use.

Nine site responders (seven Trusts) in Group B trained on average between 11 and 150 staff, either through direct training or through cascade training systems. One tertiary Trust (Group B) trained around 400 staff in order to support provision of PO screening including community midwife teams. Another tertiary Trust in Group B commented that their training numbers were too numerous to detail. One Trust highlighted that it was important for individual Trusts to be given the flexibility to decide which staff should provide PO screening as, to work well, screening needed to be consistent with existing local staff roles and practice.

A training needs analysis undertaken locally by the pilot Trusts was supported with educational resources provided by the pilot project team. Overall 14 site responders (93%) found the educational resources provided to be useful in preparing staff to undertake PO screening. In one Trust, staff noted that the training programme offered was very effective in giving staff the confidence to perform PO screening. Respondents were asked if there were any issues identified locally with the training provided in performing the PO screening and staff from three Trusts identified minor issues, including the training film being too detailed and not focused on the practical issues, cascade training being unreliable and some corrections required to technique after re-evaluating staff.

Table 43 provides details of the staff disciplines and numbers of staff trained where provided from the pilot Trusts. The PO screening training programme undertaken by those Trusts providing training was just a onetime requirement and not on-going. Training was provided across a spectrum of maternity service disciplines. The disciplinary groups who performed PO screening as part of the pilot were as follows:

- Midwives
- Neonatal nurses including ANNPs
- Paediatric medical staff
- Hearing screeners
- Nursery nurses
- Maternity care/support workers

Table 42: Multidisciplinary staff training to implement pilot PO screening

Trust	Staff disciplines and training numbers
Group A (already performing PO screening prior to the pilot)	
Bradford Teaching Hospitals NHS Foundation Trust	Training needed only on use of equipment (staff numbers not available/not provided)
Cambridge University Hospitals NHS Trust	65-70% (number not provided)of midwives and maternity support workers
Countess of Chester Hospital NHS Foundation Trust	All midwives who performed NIPE examination already proficient in PO screening. Many new starters during the pilot period. Overall 150 midwives by the NIPE midwife. Junior medical staff trained (nos. not provided).
Norfolk & Norwich University Hospitals NHS Foundation Trust	No numbers provided
Northern Lincolnshire and Goole Hospitals NHS Foundation Trust	Additional training not required
The Royal Wolverhampton Hospitals NHS Trust	All members of staff were trained, midwives, Paediatricians, neonatal staff including support workers (not clear if these staff groups were already trained)
Warrington and Halton Hospitals NHS Foundation Trust	No additional midwives or neonatal nurses trained. Training given to the new doctors on induction during pilot approx. 8
Group B (commenced PO screening as part of the pilot)	
Brighton & Sussex University Hospitals NHS Trust - Royal Sussex Hospital site Princess Royal Hospital site	 6 nursery nurses, all junior doctors trained on Induction and some midwives(? 5) 5 Nursery Nurses,1 midwife, 8 ANNPs and midwives had cascade training (nos. of midwives to provided)
East Cheshire NHS Trust	59 staff trained, which consisted of 30 midwives, 1 ANNP, 3 paediatric nurses, 1 registered nurse, 1 Maternity Care Assistant and 24 doctors.
Hull & East Yorkshire Hospitals NHS Trust	Approximately 150 staff. No breakdown of disciplines provided
Liverpool Women's NHS Foundation Trust	Too numerous to give an accurate figure. All Maternity Support Workers plus shift leaders were initially trained and then midwives
United Lincolnshire Hospitals NHS Trust Lincoln County Pilgrim Hospital	Over 20 staff comprised of 10 hearing screeners, 1 manager, all new SHO doctors every 4 months

University Hospitals of Leicester NHS Trust Leicester General Leicester Infirmary St. Mary's Birth Centre	In total approximately 300 midwives, 33 nursery nurses and neonatal nursing assistants, 50 junior doctors, 9 consultants and 8 ANNPs
Wye Valley NHS Trust	Approximately 20 doctors approximately 30 midwives
York Teaching Hospitals NHS Foundation Trust – York Hospital site Scarborough General Hospital site	 100 midwives All midwives. No numbers provided

The number of staff that required PO screening training in particular within the tertiary Trusts reflects the scale of the hard work undertaken and commitment of the pilot Trusts with the implementation.

Some examples of training programmes were provided by Trusts. The cascade model of training was identified by four Trusts. One Trust in Group B commented that all the maternity support workers and shift leaders were trained in the first instance followed by the midwives on a rolling basis. In two other Group B Trusts training was conducted on a cascade basis. The Trust in Group A that required additional midwives to change to the screening pathway had additional midwives trained by the NIPE midwife. The PO screen training was also scheduled as part of in-house study days alongside 'ad hoc' training sessions. The paediatric junior medical staff were trained by the senior paediatricians.

There was a practice change for three of the Group A Trusts in respect to the site of the PO screen measurement. These Trusts measured only the post ductal reading prior to the pilot. All three Trusts changed practice to both pre and post ductal readings as part of the pilot hence the need for additional training. Four of the Group A Trusts already performed pre and post ductal measurement readings and used the same pulse oximeter model as those provided by the pilot project team.

The minimal additional training requirements for four of the Group A Trusts would suggest this would be the case for Trusts already performing PO screening nationally should there be any national rollout programme. Additional training would be required if the local screening pathway differed significantly from any screening programme pathway.

One Group B Trust commented that the cascade training was an extra task but staff became 'accustomed very quickly to the new way of working'. Another group B commented about the training for the hearing screeners in that they felt they needed more training but their confidence improved due to the low numbers of screen positive cases.

Equipment provision

The pulse oximeters were provided to the pilot Trusts by the pilot project team. As part of the device provision contract the manufacturer offered and provided local on-site training to the pilot sites. For the purposes of the pilot it was important to evaluate the use of the devices and any potential functional problems identified with either the device or as a result of operator error.

Of the 17 site responders, 11 did not experience any problems with equipment. Six respondents did encounter problems, including machines not working properly (n=2), difficulty getting probes to fix on (n=2), and fluctuating readings (n=2). Most sites used Coban tape for fixing the probes (n=7), two used Masimo blue wraps but one noted that these were expensive. While the others used micropore, transpore, velcro and hypafix.

One consultant in a Group B Trust suggested that the higher specification model of the pulse oximeters provided for the pilot would have been more appropriate for PO screening to eliminate any ‘fluctuation’ in the measurement reading.

One Trust independently purchased additional devices for the community midwifery service as the large number required would have greatly exceeded the quota of devices supplied. There was a contingency provision of extra devices for Trusts that required them to reduce the risk of screens not being performed due to a lack of equipment. It was advocated that the equipment provided for the pilot be used for both the first and any repeat screens for consistency and to reduce operator error. All sites used the same devices for repeat screens except for one.

Parental perspectives

Staff in screening sites were asked if they felt that parents understood the information leaflet provided and if any specific concerns were raised by parents taking part in the pilot. In 16 of the 17 site responders, staff were of the view that parents understood the information leaflet adequately. One Trust did not comment. Four respondents noted that a few parents voiced concerns, including declining the screen because they thought it would be painful (n=1 baby), or it involved radio waves (n=1 baby). In one site, parents complained that the leaflets explaining the PO screen were only available in English. Staff in one Trust noted that parents appeared ‘reassured’ by the PO screen.

Additional views of staff involved in the PO pilot

Staff who were interviewed were also offered the opportunity to comment about any aspects of the screening pilot that they felt were also relevant.

Group A comments

The Trusts in Group A offered fewer comments overall than the Group B Trusts. One Group A Trust commented that implementing the 4-8 hour timing for the 1st PO screen had been difficult due to the existing workloads of the midwives. However, since making the change as part of the pilot they would continue with the pilot screening pathway post pilot. Two Trusts in Group A commented positively. One Trust commented that PO screening was 'cheap, portable, easy and quick' and accepted by all staff who were supportive of the process. Another commented that the pilot was 'a good experience'. This Trust changed from post-ductal to pre- and post-ductal site measurements.

One Group A site did not change its local screening pathway and adopt the pilot screening pathway at any point; staff from this Trust stated that they would 'await national recommendations following the pilot' before considering altering their existing local screening pathway.

Staff from one site commented that they were concerned that PO screening increased staff workload significantly and had resulted in only one serious CHD case being identified.

One Trust in Group A did not have any additional comments to offer.

Group B comments

Staff in four Group B Trusts stated that they felt very positively about continuing PO screening after the pilot as it was simple and easy to administer; staff in one site noted that it reassured staff and parents when sending babies home, particularly if it was an early discharge. Staff in another site noted that screening identified babies with a range of problems so that 'even if only one cardiac baby was identified'; they would consider it a useful test. Another Trust commented PO was 'picked up other problems easy to do and quick'. Another Trust commented 'Excellent screening tool. Agree fully with PO'. Staff in one Trust commented that although they would like to continue PO screening, but stated the local commissioners would not fund continuation of the programme unless it was recommended by the UK National Screening Committee. This Trust has continued to provide PO screening post pilot.

Two Trust in Group B commented that since the start of PO screening as part of the pilot there had been no 'crash calls' or admissions of babies in a 'collapsed' state.

Summary

The key findings from the interviews with staff in the pilot Trusts can be summarised as follows:

Adherence to the pilot screening pathway

- One Group A and five Group B Trusts failed to adhere precisely to the pilot screening pathway; specifically they did not perform PO screening at 4-8 hours after birth but varied the timing to suit staff availability, timing of discharge and integration with existing NIPE screening model.
- Two Group A Trusts who already had a PO screening test as part of the NIPE exam continued with this model and did not adopt the pilot screening pathway which required the PO screen to be undertaken at 4-8 hours after birth
- Seven responders would admit a baby to the NNU with a PO screen positive outcome whilst ten would not. Some Trusts commented that the baby would be reviewed on the postnatal ward before. The baby would be admitted to the NNU if clinically indicated or further investigations warranted. Nine responders would have a baby that required a repeat screen reviewed by a senior paediatrician; eight would not whilst other Trusts said that an ANNP or paediatric SHO would review the baby at this point.

Staff training and equipment

- Trusts varied in the staff disciplines that were trained to implement the pilot screening pathway. This depended on existing local staff roles; no Trusts recruited additional staff to undertake PO screening
- One Trust would consider recruiting more nursery nursery nurses
- Most Trusts found the educational resources provided were effective for training staff at all levels to perform PO screening confidently
- Trust staff experienced few problems with equipment.

Burden on neonatal and cardiology services

- Although most Trusts did not find the increased number of neonatal unit admissions to be a burden. One consultant in one Trust considered stopping the pilot during two months when the neonatal unit had a cot shortage. However after discussion with the other consultants it was agreed that the benefits of the PO screening outweighed the risks and the pilot was not interrupted
- Trust staff were not aware of any increase in the number of echocardiograms or cardiology consultations requested during the pilot.

Recording screen results

- Most problems noted by staff in pilot Trusts were related to the use of the NIPE SMART IT system for entering the PO screen results. Although some problems could be addressed by improvements to the IT system, several Trusts noted that it was not possible for the screener to record all screen results at the time of the screen and some had to be entered retrospectively. In addition some Trusts entered the PO screen results at the time of the NIPE examination
- There was a delay in the entry of PO screening results to the NIPE SMART system for those babies screened in the home environment.

Parental concerns

- No significant concerns were identified to suggest that PO screening would be unacceptable to parents.

Views of local staff on continuing screening

- All Trusts agreed that they wished to continue with PO screening post pilot and have continued to do so.
- Four Group B Trusts had a positive view of the pilot and wished to continue screening; one noted that funding would be dependent on a national recommendation to implement screening.
- Seven Trusts overall provided positive comments about PO screening
- Three Group A Trusts did not alter the established local pathway for the pilot and was only willing to do so if a new pathway was based on a national recommendation to implement a standardised screening pathway
- One Trust considered that the number of babies identified with non-cardiac problems was a benefit of the screening programme and that the programme was useful even if few cardiac babies were identified
- One Trust did not consider the extra workload involved in offering universal PO screening was justified by the number of cardiac cases identified.

Resources and Needs

Mapped pilot objectives:

- develop information for parents and resource media for health professionals to be used in the pilot
- support implementation of training for health care professionals involved in newborn screening using PO in the pilot.

Educational resources

As part of the pilot strategy it was essential to provide professional and educational resources to support the training needs of health care professionals in performing newborn PO screening to ensure a consistent approach. In addition, information resources were produced for parents to support understanding of the screening process and their potential participation in the pilot.

Production of written and visual material was a critical element of the pilot planning process and considerable amount of work was undertaken in their production. This included consultation with key stakeholders such as user groups Tiny Tickers and Children's Heart Federation who were consulted in the development of the parents information leaflet.

The suite of documents consisted of:

- clinical management toolkit for health care professionals – quick reference guide excerpt (Appendix 13)
- information 'flyer' for health care professionals (Appendix 9)
- information for parents including reference to consent (leaflet) (Appendix 10)
- information 'flyer' for use for use in public areas in participating Trusts (Appendix 11)

A large piece of work was undertaken to produce a newborn PO screening information film. The film was made available to all pilot Trusts for use in local training sessions and consisted of practice-based footage of undertaking PO screening, visual animations describing physiology of the fetal and newborn circulation and voiceovers to illustrate key elements of the screening pathway. There was a robust tender process for the award of the contract to produce the animation section of the film resource. The overall film development process included:

- production of storyboards and scripts – excerpt of storyboard attached as appendix 16
- production of a voiceover recording
- filmed sequence footage of how to perform PO screening in the newborn (filmed at a London Trust with newborn babies and their parents)

- still photographs taken for inclusion in the parent and health care professional literature.
- development of detailed animation to relate theory to practise and demonstrate fetal, transitional and newborn circulation and patent ductus arteriosus
- development of succinct accompanying text to support images

The educational resources produced to support the pilot offered a consistent approach to performing newborn PO screening with the aim of minimising potential operator error that may result in an inaccurate point of care result.

Local training

In order to ensure that the workforce was competent to undertake PO screening each participating Trust undertook a local training needs analysis to assess local skill sets. Training sessions were then arranged for the diverse workforce, some of whom had not previously undertaken PO screening and included doctors, neonatal nurses, midwives, health care assistants , midwifery support workers and newborn hearing screeners. To support the locally delivered training sessions the pilot team provided each Trust with a suite of educational resources (see below) which included information on the pilot pathway as well as offering background information on newborn circulatory physiology , the purpose of, and how to undertake, PO screening. These training sessions were supplemented by provision of onsite training by the equipment supplier on use of the designated equipment (more than one session were offered to large/ multiple site Trusts). The detailed newborn PO screening pilot clinical management toolkit was particularly well evaluated as a useful tool.

Equipment

After collaborative work within PHE to develop a pulse oximeter specification for the Pilot population (attached as Appendix 6), a formal, robust tender process was undertaken to award the contract for the provision of the pulse oximeters devices and consumables.

The equipment specification included the following requirements:

- must be suitable for use on neonates including functioning in low perfusion states
- must be motion-tolerant
- hand-held pulse oximeter device that displays the record results and is intended to be portable in normal use. Probes are connected to the unit via a cable
- accuracy of SpO_2 must comply with standard BS EN ISO 99199:2009. It states that SpO_2 must be less than ±4% over the range of 70% to 100%. To demonstrate compliance evidence from population specific neonatal clinical trials and comparison with SaO_2 must be provided

- accuracy of pulse or heart rate must comply with standard BS EN ISO 99199:2009. It states that accuracy should be supported by evidence of comparison with a reference method of measuring heart rate e.g. electronic pulse simulator of ECG heart rate specific to the neonatal population
- display must be visible in low and artificial light conditions which would be expected on maternity wards or in NICUs.

After award of the tender to medical technology company Masimo, equipment was procured and battery-operated pulse oximeters were provided to Trusts using a calculation formula based on birth-rate, number of clinical areas and geography of catchment area. Each device was provided with 3 reusable sensor cables and carry case. The additional sensor cables were to cover loss, damage and natural degradation of the sensor head. Additional sets of equipment were provided based on demonstrated case of need. In total 157 pulse oximeters and 471 cables were provided for use by participant Trusts in the pilot.

It was considered essential to use the same make and model throughout the pilot to ensure a consistent approach and increase the chance of reproducible and comparable results. As part of the agreed contractual terms, the successful bidder also provided on-site training in use of the equipment to Trusts as required prior to Phase 2 of the pilot.

Newborn pulse oximetry screening pilot Conclusions

The following form the conclusions made from the data presented from this newborn pulse oximetry screening pilot End Project Report.

During the pilot almost 33,000 babies (including homebirths) were screened in 15 Trusts following the introduction of PO screening or re-alignment of an existing screening programme to the PHE PO screening pathway.

Just over 90% of all eligible babies had pulse oximetry screening and a result entered onto the NIPE SMART IT system or local hospital information system. In babies where data was not entered a number of issues were identified relating particularly to the use of the NIPE SMART system. It is likely that more babies were screened but the result was not entered into this system.

The timing of first screening followed the agreed screening pathway in the majority of cases; however there were important exceptions to this which were mainly due to some Group A Trusts continuing with their existing service model (non-alignment with the agreed pathway). Although the vast majority of screens outside the suggested timings were within clinically acceptable limits, staff responses suggested that in the cases where screening was outside the agreed timings staff availability and timing constraints contributed to the majority of these deviations. Timing of the second screen was often outside the agreed pathway due similar constraints but this does not appear to have had clinical consequences or increased a delay in discharge.

The PO screen positive rate was 0.73% which is consistent with previously published UK studies employing early screening (within 24 hours).

In keeping with previous studies, a significant proportion of PO screen positive babies had an important clinical condition but only a minority had the target condition of CCHD. Earlier screening (within 24 hours) results in a higher proportion of babies detected with a clinical condition but at the expense of a slightly higher screen positive rate. Forty-eight percent of screen positive babies were admitted to the NNU and eight babies with the target condition of CCHD were identified by screening. A further 86 babies with significant non-cardiac conditions were also identified. The rate of true false positives i.e. babies who were completely healthy and were admitted to NNU was very low but two babies with target conditions were missed. It is clear that PO screening identifies many more babies with a non cardiac condition than those with the target condition of CCHD. The test accuracy of PO screening for these conditions is unknown and there is a possibility that some of the babies are ‘labelled’ with an

incorrect medical diagnosis thus creating the potential for over diagnosis. An attempt was made as part of the pilot to reduce this possibility but it cannot be completely excluded

There was little evidence of additional significant harm to the majority of babies who had a screen positive outcome. It is possible however, that as above some babies underwent unnecessary admission and investigation as a result of testing screen positive, particularly some of those with culture-negative sepsis, these are likely to be in a minority. There was little evidence of clinical services, including midwifery, neonatal and paediatric cardiology being overwhelmed by the consequences of PO screening. The number of screen positive cases within Trusts ranged from 0 to 52 (mean 16) which equates to an average of approximately one screen positive case every 11 days. (range 0-2 per week). Although additional work for staff and occasional pressures on admissions was described by the pilot Trusts, all were able to undertake PO screening and successfully manage the screen positive babies.

Although the majority of screen positive babies were seen by a senior clinician as recommended in the pilot screening pathway, this did not happen in every case. There were no recorded clinical consequences of this omission. A minority of screen positive babies underwent echocardiography and the additional impact on cardiological services appears to have been minimal.

No major problems with equipment were highlighted and the pulse oximeter monitors used appeared to have been fit for purpose overall. All participating Trusts have continued routine PO screening following completion of the pilot without further additional funding.

Overall the PO screening pilot appears to have achieved the main aims of demonstrating feasibility of screening without causing a significant overload to clinical services.

Strengths and Weaknesses of the Pilot

Key strengths

- The largest UK cohort of babies to date were screened successfully
- Trusts generally engaged well with the pilot process
- Comprehensive data on outcomes of all screen positive babies (not just those CCHD) has been obtained allowing robust reflection on actual clinical impact

Key weaknesses

- a number of issues relating to data collection tools as the tools were limited in their application and completion (NIPE SMART fields, Excel and ‘select survey’)
- many of the Trusts found the rigidity of the agreed screening pathway difficult to adhere to in routine clinical practice
- the Phase 1 retrospective data set was very limited which meant the direct comparison with the prospective pilot data was not possible

- the pre implementation prospective data was of limited value due to the short data collection period and the inadequacy of the data submitted
- in view of the lack of adequate retrospective data the comparison of the impact before and after the introduction of routine PO screening (in terms of frequency of diagnosis of the target conditions and secondary conditions) was not possible
- tight timescales for Trusts in preparation for Phase 2. Ideally Trusts would have time to familiarise themselves with a new NIPE SMART system well in advance of the Phase 2 prospective data collection.
- tight timescales for the provision of educational resources to support local PO screening training for the Group B Trusts prior to the commencement of Phase 2

Newborn pulse oximetry screening pilot learning points

The pilot generated a number of important learning points:

The collection of routine retrospective data regarding the number of admissions to neonatal units with specific conditions and the outcome of those conditions is a challenge. As a result, the comparator data preceding the commencement of the pilot was inadequate. A better comparator which would enable a direct comparison of the effect of PO screening on admissions and work load is required.

Although pilot Trusts who had not engaged in PO screening previously were largely able to follow the agreed screening pathway, Trusts who had an established screening model found it more difficult to adapt to the screening pathway.

Screening within a tight timeframe was a challenge for most of the pilot Trusts but a clinically acceptable screening timeframe is largely achievable.

The coordination of performing PO screening and recording the result on the NIPE SMART system was challenging for some of the participating Trusts. There appeared to have been a ‘learning curve’ and performance was better at the end than at the beginning, however, further consideration in this area is required.

The majority of babies who screened positive were healthy and did not require admission to the NNU. Further modification of the screening pathway may allow a reduction in the proportion of screen positives. Although PO screening identifies most babies with the target condition it still misses some babies and it is important that both clinical staff and parents are aware of the limitations of the test.

Most screen positive babies who are admitted to NNU have a non-cardiac condition. (i.e. not the target condition) In the majority, the early identification of these conditions is of clinical

benefit and a potentially important additional benefit of screening. However, the balance of risk to benefit for these babies and the potential cost implications needs to be carefully considered.

Echocardiography does not appear to be necessary for all screen positive cases with use of clinical judgement resulting in a minority requiring this test.

The true cost and cost effectiveness of PO screening was not defined within the pilot study and further health economic analysis is required to precisely define this.

Newborn pulse oximetry screening pilot recommendations

Following on from the data analysis of the pilot and the feedback received from the pilot Trusts relating to the agreed pilot screening pathway, the pathway could be modified in the following ways:

- timing of screening should continue to aim for first screen within 4-8 hours but a degree of flexibility earlier or later (up to 18-24 hours) is acceptable and could be considered .This may have the effect of the screening test being more easily embedded within routine clinical practice

- a second retest (third screen) could be considered in babies who are screen positive but have a normal clinical assessment and no additional risk factors. This would potentially have the effect of reducing the number of screen positive cases

Additional recommendations from the pilot:

- health economic analysis is necessary to define further the true cost of introducing PO screening

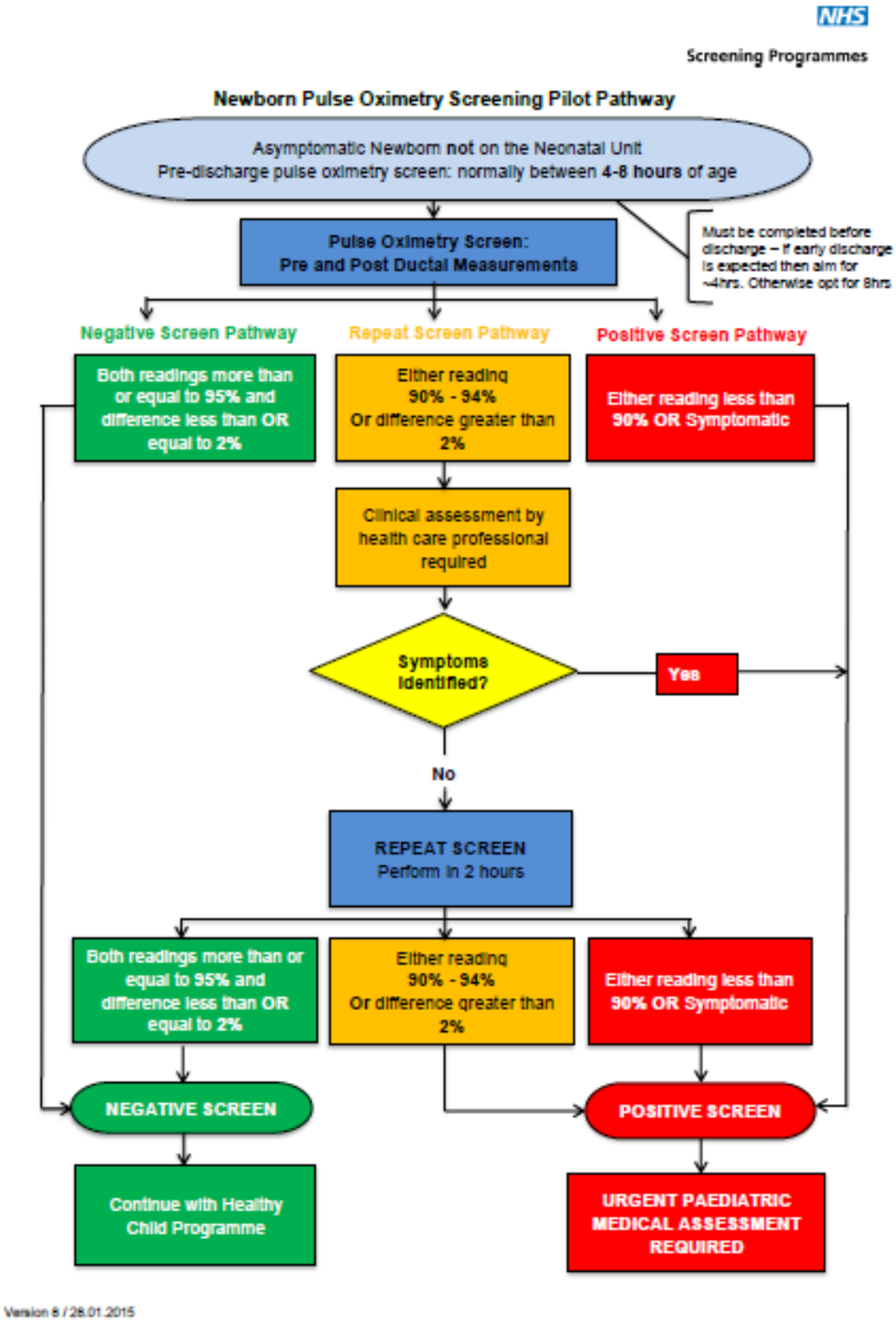
- further analysis of the effect of PO screening on admissions to NNU (particularly the non-cardiac conditions) would be beneficial including using possible use of data generated by the UK Neonatal Data Analysis Unit (NDAU)

- the risks and benefits of linking PO screening to the NIPE examination could be explored further and recommendations made

- the entry of PO screening results and relevant risk factors to one IT system (or use of interoperability messaging technology) would be beneficial to increase the recording of screening results. Additional training and support following the introduction of the NIPE SMART for the entry of the PO screen results would be advantageous

The pilot has demonstrated that in general, it is feasible to introduce PO screening in an NHS environment, however there are important clinical considerations as highlighted above. The routine introduction of PO screening could be considered once these issues have been satisfactorily resolved.

Appendix 1: Newborn PO Screening Pathway



Appendix 2: UK NSC Newborn PO Screening Pilot Project Board:

Terms of Reference

Background/Context
PO screening is to be implemented, across England as an adjunct to the current screening methodologies for detection of Congenital Critical heart Defects (CCHD) in the Newborn. The initial phases of the implementation will include a phased pilot approach.

Function of the PO Project Board
The purpose of the project Board is to take responsibility for the business associated with the PO (PO) screening project. The project Board is responsible for approving budgetary strategy, defining and realising benefits, and monitoring risks, quality and timeliness.

Role of the Project Board
The Role of the Project Board is to:

- take on responsibility for the project's feasibility, business plan and achievement of outcomes
- ensure the project's scope aligns with the requirements of the stakeholder groups
- provide those directly involved in the project with guidance on project business issues
- ensure effort and expenditure are appropriate to stakeholder expectations.
- address any issue that has major implications for the project
- keep the project scope under control as emergent issues force changes to be considered
- reconcile differences in opinion and approach, and resolve disputes arising from them
- report on project progress to those responsible at a high level, such as PHE directors, DH, NHS England
- take on responsibility for any national issues associated with the project

Role of Individual Project Board Members

The role of the individual member of the Project Board include:

- understand the strategic implications and outcomes of initiatives being pursued through project outputs
- appreciate the significance of the project for some or all major stakeholders and perhaps represent their interests
- be genuinely interested in the initiative and the outcomes being pursued in the project
- be an advocate for the project's outcomes
- have a broad understanding of project management issues and the approach being adopted
- be committed to, and actively involved in pursuing the project's outcomes

In practice, this means the individual Board member will:

- ensure the requirements of stakeholders are met by the project's outputs.
- help balance conflicting priorities and resources
- provide guidance to the Project Team and users of the project's outputs.
- consider ideas and issues raised
- review the progress of the project
- check adherence of project activities to standards of best practice, both within the organisation and in a wider context

Membership

Members should be taken on for a period of three years. In exceptional circumstances, duration of membership may be decided on an individual basis.

Member	Title / Organisation
Dr Anne Mackie	Chair Director of Screening Public Health England
Dr Robert Sherriff	National Operations Lead NHS Screening Programmes
Prof. Andy Ewer	Reader in Neonatal Paediatrics Honorary Consultant Neonatologist Birmingham Women's Hospital
Dr Matthew Cawsey	Clinical Research Fellow Birmingham Women's Hospital
Dr David Elliman	Clinical Advisor, NIPE and Newborn Bloodspot Screening Programmes
Andrew Rostron	National Programmes Lead, NHS Antenatal and Newborn Screening Programmes
Jill Walker	Programme Manager NHS Newborn and Infant Physical Examination (NIPE) Screening Programme

Claire Evans	Project Lead Newborn PO Screening Pilot
Rachel Knowles	Clinical Research Fellow Institute of Child Health
Mary Sheridan	Research Midwife Kingston Hospital NHS Foundation Trust
Adam Gregory	IT Programme and Contracts Manager NHS Screening Programmes
Steve Kawandami	IT Specialist NHS Screening Programmes
Alison Golightly	IT Consultant
Nadia Permalloo	Head of Screening Quality Assurance Development (Clinical) PHE Screening
Guled Osman	Business Manager NHS Screening Programmes
Marta Salamonowicz	Information and Research Manager Children's Heart Federation

Convenor/Chair

The Chair, (Dr Anne Mackie) shall convene the Project Board meetings.
If the designated Chair is not available, then the Acting Chair will be responsible for convening and conducting that meeting. The Acting Chair is responsible for informing the Chair as to the salient points/decisions raised or agreed to at that meeting.

Agenda Items

All Project Board agenda items must be forwarded to the administration officer for the project 14 working days prior to the next scheduled meeting.
The Project board agenda, with attached meeting papers will be distributed at least 10 working days prior to the next scheduled meeting.

The Chair has the right to refuse to list an item on the formal agenda, but members may raise an item under 'Other Business' if necessary and as time permits.

Minutes & Meeting Papers

The format of the Project Board meeting records shall be as Minutes.
The minutes of each Project Board meeting will be prepared by the administration officer and project manager.

Full copies of the Minutes, including attachments, shall be provided to all Project Board members no later than 3 weeks following each meeting.

By agreement of the Committee, out-of-session decisions will be deemed acceptable (including Chair's actions). Where agreed, all out-of-session decisions shall be recorded in the minutes of the next scheduled Project Board meeting.

Frequency of Meetings
The PO Project Board shall meet every 2 months either in a face to face meeting or by teleconference.

Proxies to Meetings
Members of the Project Board shall; shall nominate a proxy to attend a meeting if the member is unable to attend.

The Chair will be informed of the substitution at least 14 working days prior to the scheduled nominated meeting.

The nominated proxy shall have voting rights at the attended meeting. The nominated proxy shall provide relevant comments/feedback, of the Project Board member they are representing, to the attended meeting.

Quorum Requirements
A minimum of 50% of Project Board members are required for the meeting to be recognised as an authorised meeting for the recommendations or resolutions to be valid.

Declaration of interests
Members and officers should declare conflicts of interests annually; however significant conflicts should be made known, to the Chairman, as they arrive prior to meetings.

Appendix 3: Newborn Pulse Oximetry Screening Pilot Participating Trusts

Newborn Pulse Oximetry Screening Pilot Participating Trusts

Group A Trusts
Bradford Teaching Hospitals NHS Foundation Trust
Cambridge University Hospitals NHS Foundation Trust
Countess of Chester Hospital NHS Foundation Trust
Norfolk & Norwich University Hospitals NHS Foundation Trust
Northern Lincolnshire and Goole Hospitals NHS Foundation Trust
The Royal Wolverhampton Hospitals NHS Trust
Warrington and Halton Hospitals NHS Foundation Trust
Group B Trusts
Brighton & Sussex University Hospitals NHS Trust
East Cheshire NHS Trust
Hull & East Yorkshire Hospitals NHS Trust
Liverpool Women's NHS Foundation Trust
United Lincolnshire Hospitals NHS Trust
University Hospitals of Leicester
Wye Valley NHS Trust
York Teaching Hospital NHS Foundation Trust

Appendix 4: NPS Project Deliverables from agreed NIPE SMART PO Data Fields Criteria

	1) Enhance the NIPE SMART 'PO' module to reflect the PO dataset and support the new Newborn PO Screening Pathway.	2) Approved change requests to the NIPE SMART PO module, are delivered within an agreed timeframe.	3) Provide system users with support and training of the NIPE SMART PO system.
	Deliverable Measures		
a.	Changes to the system are available on-time and are successfully tested and approved by the Programme Team.	Changes to the system are: • tested and approved by the Programme Team and; • released into the 'Live' environment at agreed timescales.	Key users trained in the use of the system prior to pilot start date.
b.	Users are able to enter the required dataset within the new PO screens.	Develop reports to provide the Programme Team with the ability to; • monitor pilot site activity and • evidence success of the new pathway and data collection mechanism.	Help Desk is set up to log calls and support pilot site users.
c.	Changes to the system meet the user requirements as defined in PO Screen Phase 1 Changes and PO Screen Phase 2 Changes.	Develop report to enable sites to monitor their local activity.	Consultancy support: provide advice and guidance on functional requirements, training, feedback mechanisms and lessons learned.
	System allows users to record or view the	**Programme and site reports**	**Project Management: delivered pilot**

following key information: • **Oxygen saturation results for the pre and post ductal measurements** • **differential thresholds** • **timing of the first screen** • **timing of repeat screen**	**present the data, as agreed by the reporting advisory group.**	**on time and provided clear implementation communications.**
System is available to the pilot sites users between 1st July – 31st December 2015, between the hours of 07:00 – 19:00 (Core Service hours), for example: • **agreed number of upgrades during the Pilot period** • **agreed number of scheduled 'down time' during the Pilot period** • **number of 'unscheduled 'down time' during the Pilot period**	Programme and site reports are available by August 2015.	

Appendix 5: Project Initiation Document (PID)

7 May 2015

NIPE Programme Team is to implement a NIPE SMaRT PO Solution.

This document describes the project to implement the Solution and how the project will be managed.

Distribution:

Name	Job title
Claire Evans	Newborn PO Screening Pilot Project Lead
Jill Walker	NIPE Programme Manager
Andrew Rostron	Newborn PO Project Board Member
Dr David Elliman	Newborn PO Project Board Member
Professor Andy Ewer	Newborn PO Project Board Member
Dr. Matthew Cawsey	Newborn PO Project Board Member
James Walker	IT Consultant, Newborn PO Project Board Member
Steve Kawandami	Antenatal and Newborn Screening IT Consultant, Newborn PO Project Board Member
Clare Jones	Project Lead, NIPE Programme
Rebecca Ward	NIPE Implementation Lead
Caroline Junor	NPS Project Business Consultant
Alan Campbell	NPS Head of Screening

Document control:

Version	Description	Release date	Reason for change
0.1	PO Project	19 March 2015	Initial draft
0.2	PO Project	7 May 2015	Second draft after changes to plan
1.0	PO Project	12 May 2015	Document released for submission to Project Board

Prepared by:

Name	Contact details
Julia Morrison NPS Programme Manager	07983-457815

Table of Contents

Introduction

Document Purpose

This document describes the project and how it will be managed. It must be read in conjunction with the Project Plan, which defines the detailed stages of the project at activity level. The PID and plan together form the overall project baseline, against which progress will be tracked.

Project Context

Public Health England's Newborn Physical Infant Screening Examination Programme (NIPE) has been tasked with piloting the introduction of PO technology as an additional screening test to the existing newborn screening programme. PO improves the detection rate of serious forms of Congenital Heart Disease (CHD) As a secondary target PO can aid the detection of other conditions in the newborn baby e.g. infection or respiratory problems.

The PO test involves placing a small probe on the baby's finger and either foot and measuring the oxygen levels within the blood. The pulse oximeters device attached to the probe provides the healthcare professional with a reading which indicates whether the baby's oxygen blood levels are normal or lower than expected.

Lower levels of Oxygen can be a marker for CHD and other problems e.g. respiratory problems, and depending on how low the levels are below the 'lower threshold' the baby will either be retested after a period of time or transferred to an NICU/SCBU unit for further tests and observation.

The more sensitive PO test is likely to identify babies with a serious CHD which previously would not have been diagnosed prior to discharge from hospital. Early diagnosis and timely intervention for these babies has a much better outcome rather than babies being discharged home undiagnosed and requiring subsequent emergency readmission and management in hospital.

To support the PO implementation programme, there is a need to modify and enhance the NPS SMaRT Newborn Infant Physical Examination (NIPE SMaRT) to support the additional data capture, pathway support, equipment integration and antenatal CHD risk factor notification.

The enhancements and modifications will be undertaken through 4 discrete developments, driven through an 'Agile' based development approach. NPS Public Services will aim to deliver the 4 releases of the NIPE SMaRT application between March 2015 and March 2016 with releases timed to meeting the specific needs of the PO change programme. This PID defines the scope of work to deliver the first two releases:

- **Release 5.4 (now 5.3): The capture and searching of PO test data**
- **Release 5.5 (now 5.4): Pathway compliance, Decision Support and Reporting**

Project Definition

Objectives

To develop, test and release two sets of changes to the NIPE SMaRT application software which will be tested as part of the Newborn PO pilot plus develop a set of reports which will be used by the programme team to assess the pilot.

To work alongside the Programme Team in supporting the pilot sites in the use of the new PO software.

Scope

The project is to deliver 2 NIPE PO related software changes:

- CCN15-01 - **Release 5.3: The capture and searching of PO test data**
- CCN15-02 **- Release 5.4: Pathway compliance, Decision Support and Reporting**

Exclusions & Constraints

Both releases of software are to be used by the pilot sites to collect data which will be used to assess the pilot and therefore the software needs to be available by 1st July.

Pilot reports need to be available a month after the start of pilot, early August.

Assumptions

'Agile' development method will be used to define requirements, agree contents of the releases, development and testing.

The Programme Team will be responsible for confirming the details of the requirements.

The Programme Team will be responsible for testing and signing off the releases as acceptable to be deployed in the Live environment.

The Programme Team will be responsible for communicating information about the new software to the pilot sites with support from the NPS project team.

Stages & Deliverables

Stage 1 - Initiation

No	Key Deliverable	Owner	Approval
1	This Project Initiation Document (PID) and Plan	Julia Morrison	Claire Evans
2	Risk Register	Julia Morrison	Claire Evans
3	Stage Acceptance	Julia Morrison	Claire Evans

Stage 2 - Rel 5.3 PO Changes

No	Key Deliverable	Owner	Approval
1	PO changes (Rel 5.3)	Caroline Junor	Claire Evans
2	User Acceptance Report	Caroline Junor	Claire Evans
3	Monthly Highlight Reports	Julia Morrison	Claire Evans
4	Stage Acceptance	Julia Morrison	Claire Evans

Stage 3 - Rel 5.4 PO Changes & Reporting

No	Key Deliverable	Owner	Approval
1	PO changes (Rel 5.4)	Caroline Junor	Claire Evans
2	User Acceptance Report	Caroline Junor	Claire Evans
3	Reports	Caroline Junor	Claire Evans
4	Monthly Highlight Reports	Julia Morrison	Claire Evans
5	Stage Acceptance	Julia Morrison	Claire Evans

Stage 4 - Setup Pilot Sites

No	Key Deliverable	Owner	Approval
1	Sites setup	Julia Morrison	Caroline Junor
2	Populated pilot reports	Caroline Junor	Claire Evans
3	Stage Acceptance	Julia Morrison	Claire Evans

Stage 5 - Project Close

No	Key Deliverable	Owner	Approval
1	Closure Report	Caroline Junor	Claire Evans
2	Benefits Realisation Report	Caroline Junor	Claire Evans

No	Key Deliverable	Owner	Approval
3	Stage Acceptance	Julia Morrison	Claire Evans

4 High Level Plan

	Start	End	Owner
Stage 1 - Project Initiation	**05-Jan**	**07-Mar**	
Project Start	05-Jan	05-Jan	
Workstream - PO Smart System Updates	**05-Jan**	**31-Dec**	
Release 1 - Initial PO Software changes	05-Jan	01-Apr	NG
Release 1 Live (NIPE 5.3.1)	08-Apr	08-Apr	NG
Stage 2 - Rel 1 (5.3) PO Software	**16-Apr**	**02-Jun**	
Warrington start testing	16-Apr	16-Apr	PT
Diana Princess of Wales (Grimsby) start testing	22-Apr	22-Apr	Site
Warrington & Grimsby trial changes - 1st week	16-Apr	24-Apr	Site
Review with users	27-Apr	27-Apr	CE,CJ
Warrington & Grimsby trial changes - 2nd week	27-Apr	01-May	Site
Review with users	05-May	05-May	CE,CJ
Warrington & Grimsby trial changes - 3rd week	04-May	08-May	Site
Review with users	11-May	11-May	CE,CJ
Software fixes/ mods (patch or next release)	12-May	18-May	DEV
Upgrade UAT (patch release)	19-May	19-May	3rd
UAT & review	20-May	26-May	PT,CJU
Signoff	26-May	26-May	CE
Upgrade Live (5.3.2)	**27-May**	**02-Jun**	**SUP**
Stage 3 - Rel 2 (5.4) Workflow Changes & Reporting	**07-Apr**	**09-Jul**	
User Requirements	07-Apr	11-May	PT,CJ
Functional requirements	07-May	20-May	DEV
Develop	21-May	10-Jun	DEV
Testing (incl regression testing)	11-Jun	24-Jun	DEV
UAT	25-Jun	01-Jul	PT
Signoff	01-Jul	01-Jul	CE
Communication (to SMART users, SMART/PO etc)	02-Jul	02-Jul	CE
Release 2 Live	*09-Jul*	*09-Jul*	*3rd*
Pilot Reporting	**29-Apr**	**31-Dec**	
Requirements review	29-Apr	29-Apr	PT,CJ,JC
Create data warehouse	30-Apr	20-May	DEV
Mockup reports	21-May	10-Jun	DEV
Review with Programme Team	11-Jun	18-Jun	CJ
Changes to reports	19-Jun	02-Jul	DEV
Review with Programme Team - 2	03-Jul	10-Jul	CJ
Signoff	10-Jul	10-Jul	CE
Update data warehouse	13-Jul	17-Jul	DEV
Agree distribution (scheduled or PT access)	20-Jul	20-Jul	CJ,PT
Interim pilot reports required	28-Sep	28-Sep	
Final pilot reports required	31-Dec	31-Dec	
Stage 4 - Setup Pilot Sites	**05-Jan**	**07-Mar**	
Send communications and documentation to sites	15-Jun	19-Jun	CE
Webex training sessions	15-Jun	26-Jun	CJU,Site
Group A	**30-Jun**	**30-Jun**	

Bradford (live-28/1/15)	30-Jun	30-Jun	Site
Countess of Chester (live-2/3/15)	30-Jun	30-Jun	Site
Norfolk & Norwich (live-27/4/15)	30-Jun	30-Jun	Site
N.Lincs & Goole (Grimsby UAT site)	30-Jun	30-Jun	Site
R.Wolverhampton (not started impl)	30-Jun	30-Jun	Site
Warrington (Live-22/7/11)	30-Jun	30-Jun	Site
Group B	**30-Jun**	**30-Jun**	
Brighton & Sussex (live-14/11/11)	30-Jun	30-Jun	Site
East Cheshire (live-14/11/11)	30-Jun	30-Jun	Site
Hull & E.Yorks (live-1/8/11)	30-Jun	30-Jun	Site
Liverpool Womens (live-4/3/15)	30-Jun	30-Jun	Site
U.Lincs (live-301/12)	30-Jun	30-Jun	Site
Univ Hosp of Leicester (live planned 23/6/15)	30-Jun	30-Jun	Site
Wye Valley (live-planned w/c 1/6/15)	30-Jun	30-Jun	Site
York Teaching (live-9/12/14)	30-Jun	30-Jun	Site
Pilot Monitoring and reporting	01-Jul	24-Mar	
PT monitoring and information gathering	01-Jul	31-Dec	PT
PT Review Findings	01-Jan	24-Mar	PT,NG
Stage 5 - Project Close	**07-Mar**	**31-Mar**	
Benefits Realisation review	07-Mar	21-Mar	CE,CJ,JM
Post Implementation Review	07-Mar	24-Mar	CE,CJ,JM
Project Handover	25-Mar	31-Mar	JM,SUP
Project Management	**11-May**	**07-Mar**	
PT Reviews (Bi-weekly)	11-May	22-Jun	JM,CJ,CE
PT Reviews (Monthly)	06-Jul	07-Mar	JM,CJ,CE

Notes:

Patch release (5.3.2) dates are provisional only and are dependent whether there are any small changes/fixes requested from the 3 week test.

Dates for implementing the pilot sites will need to be agreed with each site.

Timescales for delivering release two of the software will depend on the requirements being signed off and the plans from the development team. We will be able to prioritise the contents of the release as part of the 'agile' approach to development.

5 Project Organisation

Roles & Responsibilities

Role/Organisation/Resource	Key Responsibilities
Project Board : Executive Sponsors Programme Team - Jill Walker Andrew Rostron NPS - Alan Campbell	Provide ultimate direction and accountability for the project. Its members have the authority to ensure that their respective corporate interests are fully represented and are responsible for: Resolving any major issues Authorising Change Requests that have contractual impact Accepting the completed project.
Account Manager - NPS: Alan Campbell	Manage NPS's on-going commercial relationship with the customer.
Project Team: Programme Team NPS	Monitor project progress and risks, resolve issues and approve Change Requests. As a minimum, the group comprises a Project Manager from each organisation. Additional resources from the management, technical or user communities may be co-opted onto the group as required on either a permanent or temporary basis.
Project Lead - Programme Team: Claire Evans	Ensure customer's responsibilities, dependencies and activities are properly resourced, monitored and completed as agreed and coordinated with the relevant NPS activities. Ensure customer's user, application and technical requirements and design decisions are specified and communicated to NPS in a timely manner. Approve completed deliverables, stages and Change Requests and coordinate customer's acceptance activities. Co-ordinate lines of communication, project reporting and administration with NPS as required.
Project Manager - NPS: Julia Morrison	Ensure the project meets its time, budget and quality targets by managing the production of deliverables, securing the appropriate resources, scheduling activities, monitoring and reporting progress and resolving issues. Reciprocate the appropriate approval, co-ordination, communication, reporting, administration and reconciliation activities of customer's Project Manager within NPS.
Business Consultant - NPS PS: Caroline Junor	Point of contact for the NPS development team and the User Steering Group to clarify user requirements and to answer queries To work with Programme Centre Team and key stakeholders to clarify / confirm requirements To work with the Programme Centre Team to create and deploy site

Role/Organisation/Resource	Key Responsibilities
	training To be responsible for the project communication plan To work with the Programme Team in defining and agreeing the Success Criteria for the project Work with the NIS project manager to ensure that the project delivers everything agreed within this PID to time, to quality and to budget To provide expert opinion in the project planning process and ongoing project management To escalate risks and issues Facilitates the user workshops Ensures that all workshop decisions are documented
Development Lead – NPS PS: Amy Tighe	Responsible for managing the development team to ensure the software changes are delivered to time and to the agreed quality standards.
Business Stakeholders: David Elliman Andy Ewer Clare Jones	Responsible for representing the software requirements on behalf of the Programme Team and end users.

Control & Communication

Control

The NPS Project Manager will work closely with the Customer Project Manager to establish and maintain control through agreed procedures, meetings and reports. These controls will be driven by both fixed schedules and project events.

Progress Tracking

The PID defines the project and how it is to be managed: the Project Plan defines the detailed stages of the project at activity level. These two documents together form the overall project baseline, against which progress will be tracked. The PID and Project Plan are subject to formal approval and enable the Project Managers to authorise project activities to start as planned.

The Project Plan will be updated by the NPS Project Manager with progress using Microsoft Project.

Meetings

Title	Frequency	Attendees	Main Purpose
Checkpoint Meeting	Bi-weekly and monthly.	Project Managers Others as required	Review actions, milestones, progress against plan, risks and issues. Agree Change Requests.
Project Board Meeting	As required and at the discretion of the Board	Project Board Others as required	Represent respective corporate interests. Resolve major progress, resource, funding and contractual issues

Reporting

Title	Frequency	Circulation	Description
Highlight Report	Monthly, or as determined by Checkpoint Meetings	Programme Lead & Programme Board	Status and exceptions pertaining to milestones, progress against plan, risks, issues and Change Requests.
Checkpoint Minutes	Following each Checkpoint Meeting	Project Managers & Business Consultant	Minutes of the Checkpoint Meetings recording actions, those responsible, due date, progress, issue updates, risk updates, changes etc
Exception Report & Plan	As required	Programme Board	Risks and issues that may take the project outside normal tolerances. Impact assessment with options and recommendations to resolve them.

Risk Management

Other than those risks implied under Exclusions, Constraints and Assumptions, no specific risk assessment has been carried out in the preparation of this document.

A risk assessment will be conducted as soon as possible after project initiation has been carried out. Risks will be documented in the Risk Log with each risk categorised in terms of:

Its likelihood of occurring, on a scale of 1 to 4
Its impact should it occur, on a scale of 1 to 4
Prevention or mitigation strategy.

Risks identified during the term of the project will be notified to the NPS Project Manager and added to the Risk Log.

The Risk Log will be reviewed at each Checkpoint Meeting and contingency plans put in place for those risks that assume a high risk factor. Such risks will be included in the Highlight Report and if felt to represent issues, subject to the Issue Management procedure.

Issue Management

An issue is anything that may adversely affect the project. Issues may arise from risks that have manifested themselves or from other events that have an impact on any scheduled activity or deliverable.

Issues will be notified to the respective Project Manager who will ensure that they are documented and actioned for resolution. Outstanding issues will be included in the Highlight Report and reviewed at each Checkpoint Meeting.

Issues that pose a serious threat to the project and that cannot be satisfactorily resolved by the Project Team will be included in an Exception Report, together with an assessment of their impact and options and recommendations for resolution, and escalated to the Project Board. The Project Board will then confirm how the issue is to be resolved.

Change Control

Deliverables that have been approved may only be amended subject to the formal Change Control procedure detailed in the Supply Agreement.

Requests for change will be notified to the NPS Project Manager, who will acknowledge receipt and formally document the request on the Request for Change form. The Request will be uniquely identified and its impact assessed.

Outstanding Change Requests will be included in the Highlight Report and reviewed at each Checkpoint Meeting, where a consensus will be reached on the action to be taken. Change Requests approved by the Project Team will be referred for corporate authorisation, following which they will be incorporated into the project.

Change Requests that represent issues will be subject to the Issue Management procedure.

Stage Acceptance

When all of the deliverables and Change Requests for a stage have been approved, the Project Team will agree that the stage is complete. The stage will be reviewed and any required actions, reconciliation and administration completed. The Project Team will then formally approve stage acceptance.

Quality Plan

Approach

Quality will be managed by:

Validating and approving each deliverable against agreed criteria and standards of production

Ensuring compliance with the controls and procedures specified in this document.

Validation Criteria

By default, each deliverable will be validated for compliance against what is deemed to be its specification, the form of which will vary according to the deliverable but which will be agreed. Acceptance plans specifying the validation criteria and procedures for a deliverable may also be agreed, in which case validation will be conducted according to such plans.

Validation and Approval

Deliverables will be validated and approved as they are produced. The quality of deliverables is the responsibility of their owners, who should ensure that quality is built into the production process rather than "inspected in" after the event.

A review group will be established for each deliverable, comprising a single or number of appropriately qualified individuals including its approval authority as required. The group will review each deliverable against its validation criteria and document any defects. Changes necessary to address such defects will be incorporated and the deliverable revalidated.

Deliverables without defect or with minor but acceptable deficiencies may be submitted for approval. Approval will be signified on the deliverable itself, a control sheet, a formal Acceptance Certificate, a formal minute or other written notification as appropriate.

A complete record will be maintained of the validation and approval process including criteria used, results obtained, defects noted, changes made and approval agreed.

Documentation

The Project Managers will ensure that a complete record of all project documentation is maintained in electronic and hard copy format as appropriate, including the following:

Contracts
PID and Project Plan
Risk Log
Change Requests
Highlight Reports
Exception Reports
Checkpoint Minutes and Contact Reports
Financial Summaries
Correspondence
Workshop/training Schedules and Feedback Forms
Validation criteria and results
Defect Reports
Acceptance Certificates
Lessons Learned Report

NPS will hold the project's electronic files in a set of folders created in accordance with its standard project documentation structure, including every version of every deliverable produced.

All documents will be issued in accordance with standard version control procedures.

Project Completion

When all of the deliverables and Change Requests for the project have been approved and the final stage accepted, the Project Team will agree that the project is complete. The project will be reviewed and any final actions, reconciliation and administration completed, following which the project will be referred for final, corporate acceptance. Once accepted, the project will be closed.

After a suitable period of time in which to receive feedback, a post implementation review will be carried out and a Lessons Learned Report produced, to include:

A comparison of actual versus planned timescales and effort

A comparison of actual versus planned costs (respecting any commercially confidential information)

An assessment of how well the project achieved its objectives

An assessment of the project's failures and potential for process improvements

Support

Handover Milestones

The following key milestones regarding handing the project over to Support are included in the project plan…

Pre-Initiation of Handover – support team copied into project correspondence throughout the project

Initiation of Handover – Go-Live minus one month

Support commences – but Support team do not deal with issues alone

Full Support – Support team have full ownership of issues

Support Handover Completion

- - - End of Document - - -

Appendix 6: Newborn PO Data Management Group

Terms of Reference

The aim of this document is to provide the Terms of Reference for the Newborn PO Pilot Data Management Group.

Purpose of the Group
The aim of the Group is to ensure the safe storage and management of all data collection assimilated during the period of the Newborn PO Pilot.

Objectives of the Group
To ensure

- development of data collection tools that meet the needs of the Pilot
- identification and safe storage of all data collected as part of the Newborn PO Screening Pilot
- supervision and assurance of the submission of 'clean' and where possible of complete data at clinical level according to the relevant datasets
- formulate and agree a data management strategy that incorporates data analysis
- initiation and management of effective data analysis to inform both quarterly reports of Pilot progress to PHE and the final Pilot evaluation document
- agreement and confirmation of data reporting items and timescales for the Phase 2 data
- provision of feedback from the Meetings to the Newborn PO Screening Pilot Project Board and other relevant committees/groups as required
- identification of roles within the Group according to need in relation to the overall data management strategy

Members of the Group

Claire Evans (Chair)	**NIPE Implementation Lead, Newborn PO Pilot Project Lead**
Jill Walker	NIPE Programme Manager
Rebecca Ward	NIPE Implementation Lead.
Rachel Knowles	Clinical Research Fellow
Matthew Cawsey	Clinical Research Fellow
Steve Kawandami	IT Specialist UK National Screening Committee/NHS Screening Programmes
Adam Bruderer	Data and Information Manager, Antenatal and Newborn Screening Programmes

Responsibilities of the Newborn PO Screening Pilot Data Management Group Members and Declarations of Interest

The Newborn PO Data Management Group members should maintain professional standards of conduct and protect the reputation of the Group, advancing the interests of their particular field where relevant.

The Newborn PO Data Management Group Members shall be required to provide written notice of private, personal or pecuniary interests that they may have to the Chair. If an issue is to be considered in the area of interest the member should withdraw from the meeting whilst the Matthewer is discussed, and not participate in any discussion or vote on the Matthewer. This requirement may be varied at the discretion of the Chair should the member's interest be deemed to be not material.

Meeting frequency and Quorum for the Newborn PO Screening Pilot Data Management Group

- The Group will meet on a monthly basis for the length of the Pilot period and in the immediate post- Pilot period as required.
- Media usage of teleconferencing/WebEx/Lync can be utilised on an alternate month basis.
- The location of the meeting will be a central geographical location for all the Group members to maximise attendance.
- The Agenda, previous meeting minutes and papers for the Meeting will be distributed to all the Group members 7-10 days prior to the next meeting date. The previous meeting minutes must be presented at the next meeting so that members have the

opportunity to raise and agree amendments to the minutes before discussing Matters Arising.
- The quorum for the meeting will be 4 members of the Group; one of which must be the Chair, one Clinical Research Fellow and one IT/Data Analyst as a minimum.

Role description for the Newborn PO Screening Pilot Data Management Group members

- To read relevant papers and provide feedback where appropriate.
- Attend the Group Meetings as often as possible during the period of the Pilot and thereafter if required.
- To work together as a Team to advise on the strategic management of the data collection and analysis through effective prioritising of workload to agreed time scales
- To participate in information sharing events where data result reporting is required
- To raise issues and recommendations that have been identified by the Group with the relevant people to influence decision making and expedite and action any lessons learned
- To comply with all PHE policies in relation to the safe storage and management of data on the PHE server.
- To escalate any data management breach in accordance with PHE data management policies.
- Recognition of accountability to the Director of Programmes, UK National Screening Committee.

Standard Agenda Items

- Apologies
- Minutes from previous meeting
- Actions from previous meeting
- Matters arising
- Data management
- Data analysis
- AOB
- Date and time of next meeting

Appendix 7: Pulse Oximeter Specification

	Author	Date published
Version 2.0	Siobhan Ryan Claire Evans	20th January 2015

Background
Following publication of an HTA report on newborn PO screening in 2012 a UK National Screening Committee (UK NSC) review was undertaken. The NIPE Programme commissioned work on the cost effectiveness of adding PO to the screening pathway for the detection of critical congenital heart defects (CCHD).
Public consultation took place between September / December 2013 and the evidence presented to the UK NSC in March 2014.

The review concluded that there was value in using PO for the detection of CCHD as an adjunct to the existing newborn screening programmes for CHD (newborn and infant physical examination and antenatal fetal anomaly ultrasound screening) and found it to be cost effective.

Decision made by the UK NSC to undertake an 18 month pilot project for PO screening in the newborn.

Decision ratified by ministers in May 2014.

Aim
The aim of the pilot is to evaluate the impact of implementing newborn PO screening on NHS services and to establish feasibility for future national roll out as an addition to the existing suite of screening tests undertaken as part of the newborn NIPE examination (<72 hrs).

Pilot Methodology
Newborn PO screening is already in place in a number of Trusts across England but there is currently no national guidance or standards in place to support practice. Local pathways have been developed and outcomes of newborn PO screening are not collated at national level.
The Project Board therefore considered that, as part of the pilot and introduction of newborn PO as a new screening test, it is important to understand existing practice in a representative number of Trusts already undertaking newborn PO screening.

The pilot will therefore be conducted in two phases collating data from two distinct groups.

Phase one will:

- undertake baseline assessment and data collection in selected Trusts already undertaking newborn PO to assess the current service provision (group A).

- undertake baseline assessment and data collection in selected Trusts who have expressed an interest in implementing newborn PO screening as part of the pilot project (group B).

Phase two will:

- introduce or assure the agreed national screening pathway in those Trusts already undertaking newborn PO and collect data to record impact of any change (group A)

- introduce PO screening as a new element of the NIPE examination in selected pilot Trusts and collect data to record impact of any change (Group B)

Data collected in phase 2 will therefore offer information on the impact of change in introducing the new screening test and those who are aligning to the national protocol In line with the pilot project methodology there will be a requirement for additional more detailed local data collection, in particular for screen positive cases and those babies who are admitted to neonatal units or readmitted to hospital with a suspected CCHD. The exact data set for this is under development.

Funding

Central funding (via the NIPE Programme) to support local data collection will be available. In addition, it will be available for pilot Trusts to procure equipment (pulse oximeters) in agreement with the NIPE programme and to the defined standard specification.

General description.

The equipment must be suitable for use on newborn babies at the cot-side or in the home. It should be stand-alone (not multi-parameter) and hand held.

Scope

This specification is for pulse oximeters to be used in the NIPE Pilot for 10 months starting in May 2015. Winning the contract for the pilot does not guarantee those suppliers a place on the contract for the full national rollout.

Price and price variation

Commitment Price - Prices are dependent on the total quantity of units committed to during a mutually agreed period, between the NIPE Programme/NHS Trust/NHS

Logistics/Health Authority and the supplier, not exceeding XX months, and shall be applicable for any combination of units detailed on a single purchase order. The NHS NIPE/NHS Trust/NHS Logistics/Health Authority should submit detailed ordering schedules, including full delivery address and named contact person to the supplier at the time of ordering.

Quantity bandings.
The number of pulse oximeters that will be needed for the pilot is **131**

Delivery
Offerors are required to detail their delivery timescales for all products offered, including calibration and repairs, in working days from receipt of order. Offerors should stipulate whether this lead time would increase for large orders.

Warranty period
Offerors are required to state the warranty period for each product offered. A minimum period of twelve months warranty, inclusive of parts and labour is expected. Offerors should provide details of their policy regarding replacement of a product under the standard warranty period, for example, new for old, loan equipment provided whilst faulty product is repaired, etc.

Offerors may also submit prices for extensions to the warranty period.
Warranties are to commence when equipment is delivered and full details of serial number and despatch date forwarded to the NHS NIPE Programme.

Service and Maintenance
This contract is not for the on-going service and maintenance of the equipment offered, however offerors are required to detail the service and maintenance requirements for each piece of equipment offered.

Offerors should state whether there is any service and maintenance provision for the equipment whilst it is under manufacturer’s warranty.

Offerors are also required to state the manufacturers recommendation for frequency of calibration and the standards to which equipment should be calibrated.

Offerors should detail their policy and procedure to be followed by NHS Trusts with regard to equipment which fails during the warranty period and for equipment which fails outside of the warranty period.
Offerors are required to state whether service and maintenance information is available to provide sufficient calibration information to NHS Trusts who wish to undertake calibration and service and maintenance ‘in-house’.

Training
The pulse oximeter device training must be provided by the manufacturer. The device training must be delivered to all identified Trusts within the specified time.

A competency checklist for the device should be available for use by Trusts to assess staff competency in the use of the device. Any additional training and educational resources for the device should be made available.

Changes or upgrades to the contracted specification (required by programme or from supplier) Not applicable to the pilot.

CE marking
All products, including software, must be CE marked under the Medical Devices Directive. Evidence of which level and how certification was achieved must be provided. Contractors must provide details of the notified body with whom they are registered. Software must comply with DSCN 14/2009Patient Safety Risk Management System-Manufacture of Health Software. DSCN 18/2009 Patient Safety Risk Management System-Deployment and use of Health Software.

Environmental
Equipment must be suitable for use within NHS e.g. be resilient to hygiene procedures and be suitable for use at the cot-side or in the home. It must comply with IT configurations used in the NHS e.g. Windows and Internet explorer versions and operate within NHS Information Governance constraints The Offerors will comply with all obligations imposed on them by the Waste Electrical and Electronic Equipment Regulations 2013 in relation to products that are subject of the contract.

Product history
Offerors should detail the product history up to the current issue / revision level, in terms of detail of upgrade, from when equipment was launched. History must be relevant to the neonatal population.

Provision of spare/maintenance
Calibration and repairs must be carried out promptly, minimising screening down time. Offerors must state the time frame for replacement of parts, for repairs and calibration whether they be carried out on site or require a return to the factory. Costs for the various options must be stated.
Offerors are required to guarantee the supply of spare parts and the provision of maintenance and repair services for minimally five years from the expiry of this agreement or the withdrawal from sale.

Product Literature

Offerors are required to submit a user manual and technical manual, in English, for each item of equipment offered and must accompany this offer. The user manual must include the manufactures recommended hygiene control procedures.

Technical specification
The following gives a framework of essential and desirable features/functions of the equipment to be used. The desirable features will be considered during the evaluation / award process on a value for money basis.

Where contractors are asked to provide test results that “can be independently verified” these may take the form of peer review articles in journals, independent reports carried out on the contractor’s behalf or summary data that the company submits for inspection by the designated evaluation team.

All articles, test results and data should explicitly describe the protocol used to achieve the results and the name(s) of the person(s) who can be contacted to verify the protocol used. If the journal articles do not include sufficient information on protocol, then an additional submission detailing the protocol should accompany the article.

We appreciate that for many screening devices ‘desirable features’ are a luxury or indeed an encumbrance in some instances. However, in this section, part of what we wish to explore is the flexibility that the offered equipment has to respond to future changes in protocol that may be deemed desirable or beneficial in the light of experience and research evidence.

Essential

E1 Must be suitable for use on neonates including those with low perfusion states
E2 Must be motion tolerant
E3 Hand held pulse oximeter device that displays the record results and is intended to be held in the hand in normal use. Probes are connected to the unit via a cable.
E4 Accuracy of SpO_2 must comply with standard BS EN ISO 99199:2009. It states that SpO_2 must be less than ±4% over the range of 70% to 100%. To demonstrate compliance evidence from population specific neonatal clinical trials and comparison with SaO_2 must be provided.
E5 Accuracy of pulse or heart rate must comply with standard BS EN ISO 99199:2009. It states that accuracy should be supported by evidence of comparison with a reference method of measuring heart rate e.g. electronic pulse simulator of ECG heart rate specific to the neonatal population.
E6 Display must be visible in low and artificial light conditions which would be expected on maternity wards or in NICUs.

E7 Must have removable, rechargeable batteries so that it can be used at the cot-side or in the home and have sufficient capacity for use throughout typical working day.
E8 Sensors should be re-usable and resilient to frequent cleaning.
E9 A suitable carry case must be provided for safe transportation of the equipment between clinical situations and community.

Desirable

D1 Methods and products recommended for the securement of the sensor to babies' limbs must be cost effective to encourage best practice with is one use only. The options must be described.

Appendix 8: Letter Template

NHS

Screening Programmes

Newborn and Infant Physical Examination

Floor 2, Zone B
Skipton House
80 London Road
London SE1 6LH
T +44 (0)20 3682 xxxx
newbornphysical.screening.nhs.uk
@PHE_Screening

6th May 2015

Dear Colleague,

Re: Newborn Pulse Oximetry Screening Pilot

I am writing to you to inform you about the National Newborn Pulse Oximetry Screening Pilot which is currently taking place in 15 participating Trusts across England.

The aim of the pilot is to evaluate the impact of implementing newborn pulse oximetry screening on NHS clinical services and to establish feasibility for future national roll out as an addition to the existing suite of screening tests undertaken under the auspices of the Newborn and Infant Physical Examination (<72 hrs.).

The project is being led by Newborn Pulse Oximetry Screening Pilot Lead, Claire Evans and Jill Walker, Newborn and Infant Physical Examination Programme Manager.

Considerable work has been undertaken over the past few months in the development of the pilot methodology and a suite of documents to support the project and Trusts are now submitting a retrospective data set to understand current service provision and clinical outcomes for neonates.

From July 2015, participating Trusts will be required to submit prospective data for babies screened and for those who are screen positive using the nationally developed newborn pulse oximetry screening pathway. In line with the project methodology, more detailed analysis of screen positive outcomes will be assimilated at local level using a bespoke data collection tool. Data collection in this phase will run until 31st December 2015.

This prospective data collection will offer information on the impact of change in introducing the new screening test (or aligning to the pathway) and will enable collation of important information on coverage and the referral pathway for screen positive cases. Although the pilot team do not require any patient identifiable data, I wanted to inform you that participating Trusts will be seeking outcome data from you for babies referred and treated by your centre. It would be very much appreciated if you could ensure that they have the prompt feedback required to ensure complete data submissions.

Public Health England is responsible for the NHS Screening Programmes

Please see Appendix 1 for list of participating Trusts for your information and appendix 2 for data set in relation to cardiac outcome data

For further information please contact Jill Walker, NIPE Programme Manager jillwalker1@nhs.net or Claire Evans, Newborn Pulse Oximetry Pilot Lead Claire.evans9@nhs.net

With many thanks in anticipation

Yours sincerely,

Dr Anne Mackie
Director of Screening Programmes

PHE Gateway number 2015-042

Appendix 9: Information ‘flyer’ for health care professionals

NHS

Screening Programmes

Newborn and Infant Physical Examination

Newborn Pulse Oximetry Screening Pilot: Information for healthcare professionals

Background information

Newborn pulse oximetry screening to aid the detection of critical congenital heart defects (CCHD) takes place in many maternity units across England. However, there is currently no national guidance on the use of pulse oximetry as part of the newborn and infant physical examination (NIPE) screening pathway.

A UK National Screening Committee review concluded that there was value in using pulse oximetry to aid the detection of CCHD. It will support the existing newborn screening programmes for CHD (newborn and infant physical examination and antenatal fetal anomaly ultrasound screening).

The aim of early detection by screening is to reduce mortality and improve long-term outcomes for newborns with a CCHD.

This Trust will be participating in the UK National Screening Commitee Newborn Pulse Oximetry Screening pilot.

Key facts about CHD

- the incidence of CHD is 4 to 10 per 1,000 live births
- a small number of newborns will have a critical congenital heart defect (CCHD)
- not every newborn with a CCHD will have symptoms
- a small number of newborns will leave hospital with an undiagnosed CCHD. This population group are at greater risk of acute deterioration or death in the following hours or days
- timely diagnosis and intervention is crucial
- pulse oximetry as a screening tool can aid the detection of CCHDs in most non-symptomatic newborns but not all

Public Health England is responsible for the NHS Screening Programmes

Appendix 10: Information for parents including reference to consent (leaflet)

Your questions answered

How will I get my baby's result?

You will receive the result straight away from the health care professional who carries out the test. If your baby needs a referral for further assessment they will discuss this with you.

If the result is normal, does that mean my baby does not have congenital heart disease (CHD)?

We detect most cases of critical CHD through antenatal screening, pulse oximetry and the newborn physical examination.

The screening tests soon after birth may not detect babies with less severe forms of CHD.

Always seek urgent advice from a health care professional if your baby:

- is breathless
- is blue
- is not feeding well
- has low energy
- is sleepy/floppy
- has cold hands/feet
- appears unwell in any other way

Even if the result is normal, it is important your baby has their routine physical examination after the test and again at 6-8 weeks old.

5

Where can I get more information?

Your midwife, neonatal nurse or doctor can give you more information and answer any questions you have.

First published February 2015
Updated
Review due July 2015
Reference NIPEPulsOxi

How to order
Web address http://www.nhs.uk/newborninfantexam

Public Health England is responsible for the NHS Screening Programmes

6

NHS

Screening Programmes

Newborn and Infant Physical Examination

Newborn pulse oximetry screening pilot:
Information for parents

Newborn pulse oximetry screening

We use screening tests to find out if babies are at risk of a particular health problem.

We can save lives if we detect and treat heart problems early.

Research shows that the pulse oximetry test can help detect serious heart problems known as **congenital heart disease (CHD)**.

Newborn pulse oximetry screening is not currently available to all babies in England. We are offering newborn pulse oximetry screening in this hospital as part of a pilot project. The UK National Screening Committee has endorsed this project.

Screening staff will explain the test to you and will only screen your baby if you give your consent.

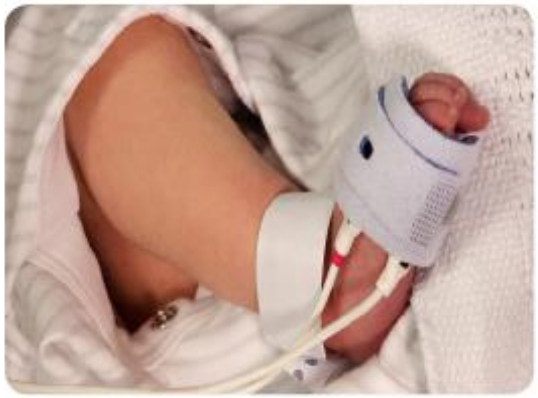
What is congenital heart disease?

Congenital heart disease (CHD) describes problems that affect the normal working of the heart in newborn babies.

The word ***congenital*** means the condition is present at birth. A small number of babies have serious, also called 'critical', CHD.

Babies with critical CHD are likely to need treatment early in life. Many babies with critical CHD have low levels of oxygen in their blood.

2



Pulse oximeter sensor attached to foot

What is the pulse oximetry test?

Pulse oximetry is a simple test that uses a light sensor to work out the level of oxygen in your baby's blood.

The test is quick, painless and completely safe. It should not distress your baby in any way.

We attach the light sensor to your baby's right hand and then to one foot.

The pulse oximeter then measures the blood oxygen level within a minute.

3

Why are we piloting pulse oximetry

A pilot is a small scale project.

We aim to gather information from this pilot to find out how pulse oximetry screening might affect other hospital services.

The government will then decide if and how to offer pulse oximetry screening to all newborn babies.

The possible results

The result of the test will be either normal or abnormal.

Normal result

Most babies will have a normal result and will not need any more tests

This does not guarantee that your baby does not have a problem but it means it is less likely

Abnormal result

If your baby has an abnormal result they will see a health care professional. The health care professional will decide if your baby should see a senior doctor or have a repeat test

Most babies who have an abnormal result do not have critical CHD. Instead they may have less serious CHD, an infection or problems with their lungs. Identifying these problems early may prevent serious illnesses

4

Appendix 11: Information ‘flyer’ for use for use in public areas in participating Trusts

NHS

Screening Programmes

Newborn and Infant Physical Examination

Newborn Pulse Oximetry Screening pilot Information for parents

What is pulse oximetry?

Pulse oximetry is a simple test to determine the amount of oxygen in your baby's blood.

Research shows that this safe, quick and painless test can help detect serious heart conditions, saving lives through early detection.

What is a pilot?

A pilot is a small scale project. The aim of this pilot is to gather information about the impact of pulse oximetry screening on other routine hospital services.
The government will then decide if and how pulse oximetry screening should be offered to all newborn babies in England.

Why is this being piloted?

Pulse oximetry screening is not available to all newborn babies in England but is being offered to your baby as part of the pilot project. This pilot will help the NHS decide if and how we can offer the test to all newborn babies in England in the near future.

When will this pilot start?

Screening with Pulse Oximetry as part of the pilot project starts at this hospital from May-June 2015.

What do I need to do to participate?

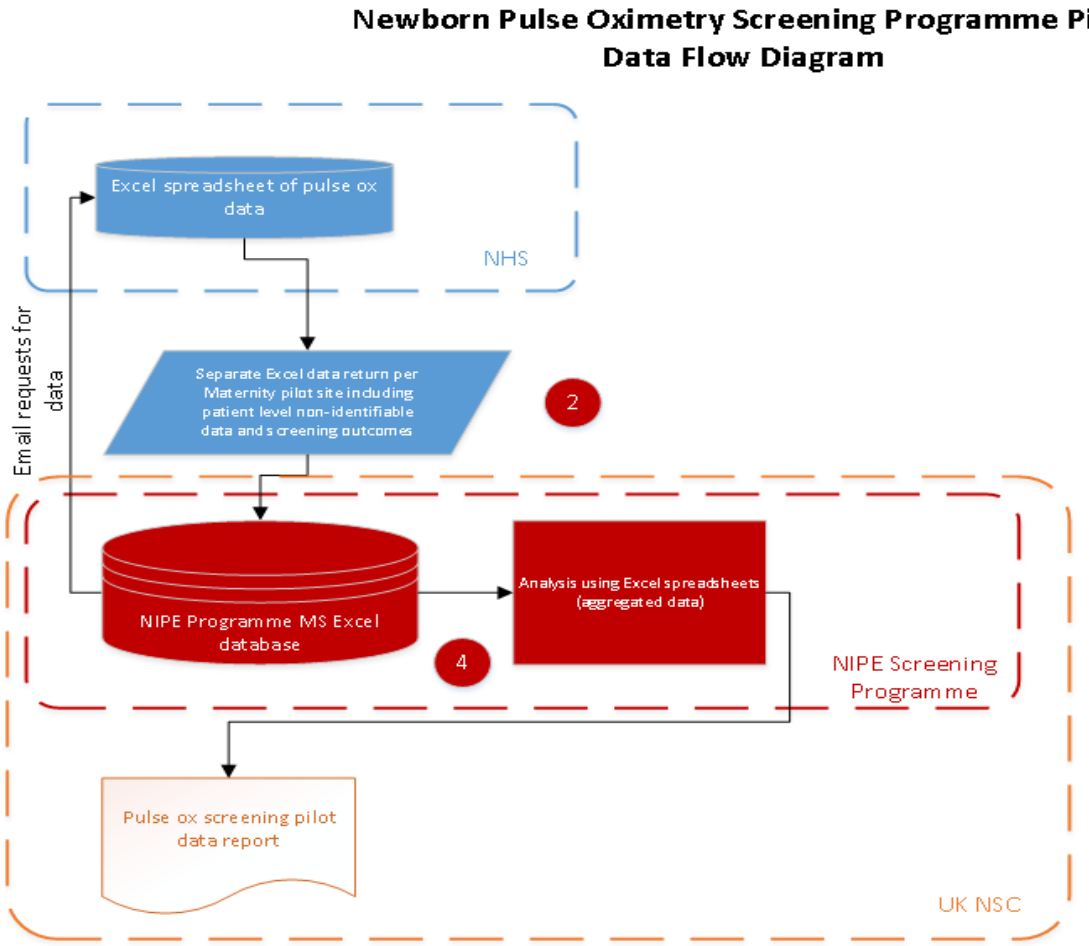
Nothing. Babies born at this hospital will be offered the pulse oximetry test before discharge. Further information will be given to you from your health care professional prior to the test. The test will not be performed on your baby without your consent.

Where can I get more information?

Your health care professional will be able to answer your questions and will provide you with a parent information leaflet on pulse oximetry screening.

Public Health England is responsible for the NHS Screening Programmes

Appendix 12: Data Flow Diagram



Newborn Infant &Physical Examination Screening

Risks and controls to mitigate risks

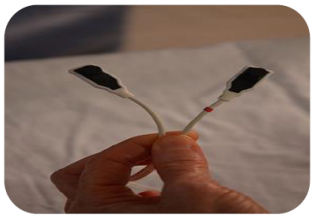
No.	Risk	Mitigation controls
1	Risk of non-responses to requests for data, resulting in gaps/ incomplete national data	Follow up missing data within a reasonable timeframe to ensure gaps are minimised
2	Risk of transcription errors on data submission (if not extracting data directly from a database)	Sense-check data returns on receipt, and request clarifications/corrections from submitting org.
2	Risk due to some forms being sent via Trust email rather than nhs.net	Accept risk – no identifiable data included, recommend nhs mail only but not all staff have nhs.net accounts
3	Risk of transcription errors in data entry to programme database	Accept risk – lack of IT systems results in scope for human error
4	Risk of databases being changed due to open access to folders within team	Accept risk – no staff other than Pulse Ox data management group need to access to shared folder

Appendix 13: Quick Reference Guide

Quick reference guide to performing newborn pulse oximetry

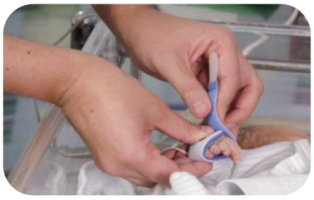
- ensure baby is eligible for screening
- perform the newborn pulse oximetry screen between 4-8 hours of age
- ensure the alarm limits are preset on the device prior to performing the pule oximetry screen

Step 1: Explanation of the pulse oximetry screen to mother/parents supported with the Parent Information Leaflet. Explain what pulse oximetry is and why the test is being offered. Take verbal consent.

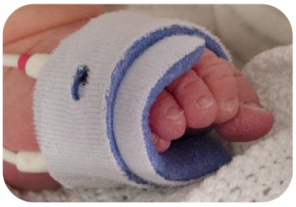


Step 2: Preparation: use appropriate pulse oximeter complete with correct multi-use sensor cable and sensor fixation materials to secure sensor to the limb. (Picture right: multi-use two arm sensor). Use decontamination gel/hand rub to decontaminate hands prior to handling the baby. General purpose detergent wipes to clean the sensor prior to and after use. Have required documentation ready to record the pulse oximetry screen results.

Step 3: Perform pre ductal pulse oximetry screen taking measurement from the right hand.



Apply the multi-use sensor. Attach with both flat slides of pulse oximeter multi-use sensor to opposing sides of the baby's right hand (picture right). The multi-use sensor has two arms. Ensure the red light emitter arm of the sensor is upper most on the top of the hand and the light detector arm is underneath on the palm of the hand. The red light emitter arm is indicated with a red band. The light can be seen when the device is switched on. Ensure both the upper and lower sensor heads are in alignment before securing the sensor to the limb. Ensure the sensor is secured to the hand correctly. Ensure a stable and consistent reading with good signal strength denoted by the signal pulse bar on the device which should be green. A suggested time would be 1-2 minutes.



Step 4: Perform post ductal pulse oximetry screen taking measurement from either foot. Attach with both flat slides of pulse oximeter sensor to opposing sides of the baby's foot. Ensure the arm with the red band is uppermost on the top of the foot. Picture right: sensor applied to foot for post-ductal measurement.

Step 5: Provide feedback of pulse oximetry screen to mother/parents

Step 6: Decontaminate the pulse oximeter device in accordance with the manufacturer's recommendations and local Infection Control Policy

Step 7: Record the newborn pulse oximetry result in the required documentation. Input the result onto the NIPE SMART system and/or alternative maternity IT system.

Appendix 14: Phase 1 retrospective data collection cardiac diagnoses

Phase 1 retrospective data collection cardiac diagnoses

Trust	Aortic stenosis (AS)	Atrial septal defect (ASD)	Atrioven-tricular septal defect (AVSD)	Bicuspid aortic valve	Coarctation of the aorta (CoA)	Complete congenital heart block	Double outlet right ventricle (DORV)	Dextro-cardia	Double aortic arch	Hyper-trophic cardio-myopathy	Hypoplastic left heart (incl mitral and aortic atresia) (HLH)
Bradford Teaching Hospitals NHS Foundation Trust	1	2	1	0	4	0	1	1	0	0	1
Countess of Chester NHS Trust	1	1	0	0	0	0	0	0	0	0	0
Warrington & Halton Hospitals NHS Foundation Trust	0	1	1	0	1	0	1	0	0	0	0
The Royal Wolverhampton NHS Trust	0	0	3	1	2	0	1	0	0	1	0
Cambridge University Hospitals NHS Foundation Trust	1	4	0	1	0	0	1	1	1	0	1
East Cheshire NHS Trust	0	1	0	0	0	0	1	0	0	0	0
Hull and East Yorkshire NHS Trust (Hull Royal Infirmary site)	0	1	1	0	0	0	0	0	0	0	3
Liverpool Women's Hospital	0	10	2	0	8	0	5	0	0	0	4
Scarborough General Hospital/ York Teaching Hospital NHS Foundation Trust	0	2	2	0	0	0	0	0	0	0	0
United Lincolnshire Hospitals NHS Trust	0	1	1	0	0	0	0				1

University Hospitals of Leicester NHS Trust	0	5	1	1	3	1	1	0	1	0	7
Wye Valley NHS Trust	0	0	0	0	0	0	1	0	0	0	0
York Teaching Hospitals NHS Trust (York Site)	0	1	0	0	1	0	0	0	0	1	0
Brighton and Sussex University Hospitals NHS Trust	0	0	2	0	1	0	0	0	0	0	0
Total	**3**	**29**	**14**	**3**	**20**	**1**	**12**	**2**	**2**	**2**	**17**

Trust	Hypoplastic right heart (HRH)	Patent ductus arteriosus (PDA)	Pulmonary atresia (PA)	Pulmonary stenosis (PS)	Tetralogy of Fallots	Total anomalous pulmonary venous drainage (TAPVD)	Trans-position of the great arteries (TGA)	Tricuspid atresia	Truncus arteriosus	Ventricular septal defect (VSD)	
Bradford Teaching Hospitals NHS Foundation Trust	0	4	2	1	3	1	2	0	0	5	
Countess of Chester NHS Trust	0	3	1	0	0	0	0	0	0	1	
Warrington & Halton Hospitals NHS Foundation Trust	0	3	0	0	1	0	0	0	0	2	
The Royal Wolverhampton NHS Trust	0	8	0	0	1	0	0	0	0	3	
Cambridge University Hospitals NHS Foundation Trust	0	12	0	2	3	0	0	2	0	5	
East Cheshire NHS Trust	0	2	0	0	0	0	1	0	0	3	
Hull and East Yorkshire NHS Trust (Hull Royal Infirmary site)	0	23	0	2	1	0	0	0	1	10	
Liverpool Women's Hospital	1	105	1	7	5	0	4	0	0	15	
Scarborough General Hospital York Teaching Hospital NHS Foundation Trust	0	2	0	0	0	0	0	0	0	5	

United Lincolnshire Hospitals NHS Trust	0	3	1	1	0	0	1	0	0	4
University Hospitals of Leicester NHS Trust	0	8	0	1	3	0	3	1	1	10
Wye Valley NHS Trust	0	2	0	0	0	0	1	0	0	2
York Teaching Hospitals NHS Trust (York Site)	0	1	0	0	0	0	0	0	0	0
Brighton and Sussex University Hospitals NHS Trust	0	40	0	0	0	0	0	0	0	1
Total	**1**	**216**	**5**	**14**	**17**	**1**	**12**	**3**	**2**	**66**

Appendix 15: Letter template to pilot Trusts re no results on NIPE SMART system

Re: 'Awaiting 1st Screen' Cohort

Dear colleagues
We are now in the final weeks of the Pilot with a completion date of 31st December for the collation of data. The achievements and progress made to date in the Pilot have been exceptional. The Project Team are extremely grateful to you all for all the commitment, hard work and enthusiasm this year with the Pilot implementation.
As you are aware from the weekly POx activity reports and from my regular emails the 'Awaiting 1st Screen' cohort remains problematic for some Trusts. In order to accurately assess the impact of PO as a new screening programme it is vital that an accurate screening coverage is demonstrated. The 'Awaiting 1st Screen' population are those babies with no screening result entered on the NIPE SMART. This cohort represents 9.4% of the total eligible babies population. The PO team consider this to be high and non-reflective of the actual position. Although this number has reduced over the months this is only proportionate to the increasing numbers of eligible babies as the Pilot progressed. This is a significant number that is impacting upon the overall national coverage which has remained at 86-87% as a consequence. It was anticipated that we could achieve a coverage of >90% nationally mid-Pilot onwards. It may well be that we have a higher screening coverage but this can't be evidenced from NIPE SMART if the screening results are not entered and consequently presents an inaccurate position.
There may be several reasons for the results of POx screens not being entered on the system:

- The screen wasn't done so therefore 'missed' – this entry can be made on SMART. It is important that we capture these data to assess the feasibility of undertaking PO as part of the clinical practice – a key aim of the pilot
- The screen was performed but the result not entered on NIPE SMART (not reflecting actual activity)
- Community babies not screened for local reasons – would be entered as 'missed' (we need to quantify who these babies are)
- Early discharge direct from the Delivery Suite – early screening can still be performed prior to discharge and these data need to be captured – again this is important data and will impact on our assessment of feasibility of implementation

I know everyone is working very hard in all the Pilot Trusts to ensure maximum screening coverage and this is much appreciated but the concern of the PO Project Board is that the data is not reflecting the true level of local clinical activity and that this will have an impact on the final analysis and thus the decision of the UKNSC when assessing feasibility of any future national roll out. In addition it is highly probable that we are also missing more screen positive cases amongst the 'awaiting first screen' cohort.

Suggested solutions to the issue:

- That in line with the local agreements between PHE and your Trust that data for the whole Pilot cohort is accounted for the screening results can be entered retrospectively and I know some Trusts have already undertaken this task. For those Trusts with a very large number of babies in the 'Awaiting 1st Screen' the list of babies can be sourced through running a pre-defined search on the NIPE SMART as shown below. It is strongly suggested that funding provided to support data collection be used to facilitate this The data clerk support funding have been provided for the purpose of data entry and submission and irrespective of how the funding is utilised at local level the data entries and submissions is requisite to the Pilot. The backlog of 'awaiting 1st

screens' could be reduced significantly through the retrospective entry of data for those babies who had screening performed.

- Stratify out the community babies that would not be screened at any point but are having an impact on the overall data set so that they can be taken into account in the overall coverage data I would require the NHS number or confidential ID number for Northgate to extract and put in a separate category
- Stratify out the 'awaiting 1st screens' after 72 hours of age as a separate column. This would help at local level to identify the cohort that have been on the system in this category for some time and therefore support data input processes.

I am very conscious of the clinical workload of everyone but to reduce the 'awaiting 1st screens' to a more acceptable 5% would be the ideal and is achievable.
I would be grateful if you could provide feedback on the suggestions of additional stratified columns. This would be one way of being able to account for at least some of the 'awaiting 1st screen' cohort in the End Project Report in March.
Many thanks
Kind regards

Claire and Jill

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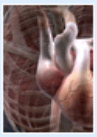
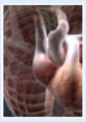
Appendix 16: Examples of comments from NIPE SMART repeat screen reasons for deviation from screening pathway

Other' category for deviating from screening pathway timing –repeat PO screen	**Examples of comments entered on NIPE SMART**
Clinical	'waiting for senior review' 'baby was on nicu - never repeated' 'baby on scbu' 'symptomatic' 'baby on the postnatal ward when I discovered they hadn't been re-check on abx' 'admitted to NNU for investigations 'baby was cold.
NIPE examination	'abnormality not identified by midwifery staff ' 'differential from 1st screen not noted by nursing staff' 'nursing staff did not note that rpt was needed' nursing staff not aware of need for rpt until 1st exam' 'need for repeat screen identified at baby check' ' 'staff performing initial screen unaware that result abnormal' '1st screen wrongly noted as normal 'not repeated as noted to have passed screening test initially' 'midwifery staff didn't recognise the need for repeat - identified when entered at NIPE examination '1st test documented as a negative result - found to need repeating when came to do EON'
Communication	'poor communication' 'need for repeat missed from handover'
Documentation	'not documented' 'nothing documented' 'unknown - not stated in notes'
Screening pathway	'saturation difference of 3% not recognised as significant at time of screening' '10 min overdue' 'unaware of need for repeat screen' 'miss-read policy'
Unknown	unsure why repeat not undertaken sooner several entries for 'unknown' reason for deviation form screening pathway

Staffing /Workload issues	‘mother in need of medical review at screening time’ ‘nobody available to perform screen’ ‘not all staff trained. had to wait for trained staff member’ ‘maternal IV access site excessively bleeding and requiring attention’

Appendix 17: Excerpt from pulse oximetry film resource storyboard

 CAMERA CLOSES ONTO ATRIUM	 CAMERA CLOSES ONTO PULMONARY ARTERY VIEW OF LUNGS AND EXCHANGE OF BLUE BLOOD CELLS FOR RED BLOD CELLS	 RESET TO HEART MODEL
CHAPTER 3 - SCENE 10	**CHAPTER 3 - SCENE 11**	**CHAPTER 3 - SCENE 12**
TIME: 0'10" VO: The blood flows from the right atrium into the right ventricle (LABELS) The blood leaves the heart through the pulmonary artery (LABEL) and is transported to the lungs where it picks up oxygen.	TIME: 0'07" VO: Gaseous exchange takes place in the lungs where carbon dioxide is released from the blood and oxygen taken up.	TIME: 0'11" VO: The pulmonary veins (LABEL) then transport the oxygen-rich blood from the lungs back into the left atrium of the heart. The blood the flows from the left atrium (LABEL) into the left ventricle (LABEL)

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 FEEDING BACK TO PARENT & CARE PATHWAY	 RESET TO FILMED BABY	 RESET TO CLOSE UP OF OPEN DUCTUS COLOURS TO SHOW MIXING BLOOD LABEL - DUCTUS ARTERIOSUS, CONNECTION BETWEEN PULMONARY ARTERY & AORTA
CHAPTER 3 - SCENE 25	**CHAPTER 4 - SCENE 1**	**CHAPTER 4 - SCENE 2**
TIME: 0'45" VO: Provide feedback of the results of the newborn pulse oximetry screen to the parent/parents and ask if they have any questions about the test itself or the result. It is important to point out here that although the screen is negative it does not mean that the baby definitely does not have a heart defect but it is less likely. A very small number of babies can have a critical heart defect but have a normal pulse oximetry screening test Record the result of the screen in the necessary documentation and input the result of the screen on to the NIPE SMART system under the Pulse Oximetry tab.	TIME: 0'07" VO: Now lets look at what happens when the duct remains open and how it may affect the pulse oximetry screen result.	TIME: 0'22" VO: As we have said the open duct can result in the mixing of deoxygenated blood from the pulmonary artery with the oxygenated blood from the aorta. This is commonly called 'shunting'. For some newborn babies with a critical heart defect the open duct maybe the only way that blood can circulate normally around the body. This is called a 'duct dependent' defect.

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